

Distal Symmetric PolyneuropathyPerformance Measurement Set

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2019 Reaffirmation Summary

In 2019, the American Academy of Neurology (AAN) conducted a triennial review of evidence to determine if the distal symmetric polyneuropathy (DSP) quality measurement set should be reaffirmed, retired or updated. The measurement set was reaffirmed, but two measures were retired due to existence of broader cross-cutting measures that made DSP-specific measures unnecessary. Additional cross-cutting measures are recommended for use as noted below.

The work group determined additional measures and updates may be needed, but such updates and development was premature without further guideline updates. This decision will be reviewed triennially.

The work group notes that measures implementation has revealed that use of exceptions may result in unintended consequences and over inflation of performance rates. As a result, users are encouraged to treat some exceptions as exclusions. For more detail please email <u>quality@aan.com</u>.

The following measures were reaffirmed:

- 1. DSP diagnosis criteria: DSP symptoms and signs
- 2. DSP diagnosis criteria: electrodiagnostic studies
- 3. Diabetes/pre-diabetes screening for patients with DSP
- 5. Querying about pain and pain interference with function

The following measures were retired:

- 4. Screening for unhealthy alcohol use
- 6. Querying about falls for patients with DSP

The following cross-cutting measures are suggested for use in the place of the retired DSP specific measures:

- Falls outcome and falls plan of care measure developed by the AAN and available in the Universal Neurology Quality Measurement Set (2018)
- Preventative Care and Screening: Unhealthy Alcohol Use: Screening and Brief Counseling developed by the PCPI Foundation and used in Center for Medicare and Medicaid Services' Merit-based Incentive Payment System as QPP 431.

The work group notes that coding in the 2013 measurement set is now out of date. ICD-10 code G62.9 Polyneuropathy, unspecified may be used to capture distal symmetric polyneuropathy. For further crosswalk of prior ICD-9 codes to ICD-10 codes for individual measure denominators and exclusions, please contact quality@aan.com

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Distal Symmetric Polyneuropathy

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2013 Desired Outcomes for Patients with DSP

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

that link to . . . Processes . . . **Outcomes** Establish and define appropriate diagnostic criteria **Proposed Process Measures** No Existing or Proposed **Proposed Measure:** Promote appropriate Outcome testing and studies **DSP Symptoms and Signs** Measures (see discussion Accurate and in the following appropriate evaluation **Proposed Measure:** section, titled /monitoring of disease Diabetes/Pre-Diabetes "DSP status and associated Screen for Screening symptoms to guide Outcomes") **PATIENT** underlying causes treatment options with DSP of condition **Proposed Measure:** Screening for Unhealthy Alcohol Use Assist patients in managing pain and **Proposed Measure:** improving quality of life Pain and Pain Interference with Function Promote patient **Proposed Measure:** safety and reduce falls Electrodiagnostic Studies **Proposed Measure:** Enhancing patient Reduce DSP safety and the complications Querying about Falls avoidance of adverse

events

2013 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. DSP affects at least one in four diabetic patients. Diabetes is one of the five major chronic conditions that affect 25% of the US community population and amounted to more than \$62.3 billion health care costs in 1996.
- 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. 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. 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. Diabetics also do not receive appropriate screening measures: only 55% obtain annual foot examinations.

Disparities

- There is currently no consistent data that shows disparities between minorities and whites for diabetes-related neuropathy and peripheral vascular disease. 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. 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 Preventative 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 ©2019. American Academy of Neurology. All Rights Reserved.

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.

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

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
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Measure Con	1
Numerator Statement	Patients who had their neuropathic symptoms and signs* reviewed and documented at the initial evaluation for distal symmetric polyneuropathy.
	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
Denominator Statement	All patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy.
Denominator Exceptions	 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	 The following evidence statements are quoted <u>verbatim</u> from the referenced clinical guidelines: 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 parasthesias 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). Other common causes of neuropathy include autoimmune disorders, tumors, hereditary conditions, nutritional imbalances, infections or toxin.

IOM Domains of Health Care

- Safe
- Effective
- Efficient

Quality Addressed

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.

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	Design	ation
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Measure purpose	 Quality improvement
	 Accountability
Type of measure	• Process
Level of	Individual practitioner
Measurement	•
Care setting	Ambulatory care
Data source	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)

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

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

AND

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).

Numerator

Patients who had their neuropathic symptoms and signs* reviewed and documented at the initial evaluation for distal symmetric polyneuropathy.

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

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

 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)

Reporting Instructions:

• For patient with appropriate exclusion criteria, report 1**XXXF1-1P**.

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

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	Measure	Components
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	onents
Numerator Statement	Patients who had electrodiagnostic (EDX) studies conducted, documented, and reviewed within 6 months of initial evaluation for distal symmetric polyneuropathy. 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.
Denominator Statement	All patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy.
Denominator Exceptions	 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	 The following evidence statements are quoted verbatim from the referenced clinical guidelines or consensus papers: 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: 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 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
- 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
- Electrodiagnostic studies are not required for field or epidemiologic studies, but the likelihood of diagnosis must be downgraded accordingly. (Formal Consensus)²³

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

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.

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

IOM Domains of Health Care

- Safe
- Effective

Quality Addressed	• 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.

Ieasure Designation	
Measure purpose	Quality improvement
	Accountability
Type of measure	• Process
Level of	Individual practitioner
Measurement	
Care setting	Ambulatory care
Data source	• 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)

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

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

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)

Numerator

Patients who had electrodiagnostic (EDX) studies conducted, documented, and reviewed within 6 months of initial evaluation for distal symmetric polyneuropathy

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 3XXXF1, Electrodiagnostic studies for distal symmetric polyneuropathy conducted (or requested), documented, and reviewed within 6 months of initial evaluation for condition or 3 XXXXF2 Electrodiagnostic studies for distal symmetric polyneuropathy not conducted (or requested), documented, or reviewed within 6 months of initial evaluation for condition or 3XXXF3, 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)
 - o 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)

 $\circ \quad \text{Append modifier to CPT II code: } \textbf{3751F-3P}$

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

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	Component	S
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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	 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	 The following evidence statements are quoted <u>verbatim</u> from the referenced clinical guidelines: 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 Improvement

Approximately 1.9 million people 20 years and older were newly diagnosed with diabetes in 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	Quality improvement	
	Accountability	
Type of measure	• Process	
Level of	Individual practitioner	
Measurement		
Care setting	Ambulatory care	
Data source	• 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)

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

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

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)

Numerator

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.

Reporting Instructions:

- For all patients meeting the denominator criteria, report CPT Category II code **1119F**, *initial evaluation for condition* or **1501F**, *not initial evaluation for condition*.
- When **1119F** is reported, also report **3754F** *Screening tests for diabetes mellitus reviewed, requested, or ordered.*

3754F Screening tests for diabetes mellitus reviewed, requested, or ordered **1119F** Initial evaluation for condition

1501F Not initial evaluation for condition

Denominator Exceptions

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

- 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)
 - o 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)
 - o 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)
 - o Append modifier to CPT II code: 3754F -3P

Axon Registry® #11: Diabetes/Pre-Diabetes Screening for Patients with DSP

These specifications have been modified at the Center for Medicare & Medicaid Services' request for implementation in Axon Registry

Measure Description

Percentage of patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy who had screening tests for diabetes reviewed, requested or ordered when seen for an initial evaluation for distal symmetric polyneuropathy and if screen positive referred to endocrinology or primary care physician.

Measure Componen	asure Compo	nents
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Numerator Statement	Patients who had screening tests for diabetes (i.e., 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, and if screen positive, referred to endocrinology or primary care physician. Suggested key phrases for use in Axon Registry include:
	Screening: • Fasting blood sugar test • Hemoglobin A1c • 2-hour glucose tolerance test Follow-up: • Referral to endocrinology • Referral to PCP
Denominator Statement	All patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy.
Denominator Exceptions	 Documentation of a medical reason for not reviewing, requesting or ordering diabetes screening tests (e.g., patient had previous diabetes screening in the measurement period) Documentation of a patient reason for not reviewing, requesting or ordering diabetes screening tests (e.g., patient declines to undergo testing) Documentation of a system reason for not reviewing, requesting or ordering diabetes screening tests (e.g., patient does not have insurance to pay for testing)
Denominator Exclusions	 Patient has a diagnosis of diabetes Patient has a known medical condition to cause neuropathy
Supporting Guideline & Other References	 The following evidence statements are quoted <u>verbatim</u> from the referenced clinical guidelines: 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 Improvement

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

- Safe
- Effective

Quality Addressed

• 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 #4: Screening for Unhealthy Alcohol Use - Retired in 2019

Suggest use of the Preventative Care and Screening: Unhealthy Alcohol Use: Screening and Brief Counseling developed by the PCPI Foundation and used in Center for Medicare and Medicaid Services' Merit-based Incentive Payment System as QPP 431.

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

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 Con	mponents
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Treasure components	
Numerator Statement	Patient visits with the patient 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 Scale ⁴⁹
Denominator Statement	All visits for patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy.
Denominator Exceptions	 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	The following evidence statements are quoted <u>verbatim</u> from the referenced clinical guidelines: • 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. 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
Improvement

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

- SafeEffectiveEfficient
- 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

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)

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

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
AND

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)

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)
 - o 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)
 - o Append modifier to CPT II code: 1502-2P

Measure #6: Querying about Falls for Patients with DSP - Retired 2019

Suggest use of the Falls outcome and falls plan of care measure developed by the AAN and available in the Universal Neurology Quality Measurement Set (2018)

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

2. American Di	labetes Association evidence grading system for chinical practice recommendations
Level of	Description
Evidence	
A	Clear evidence from well-conducted, generalizable, randomized controlled trials that are
	adequately powered, including:
	• Evidence from a well-conducted multicenter trial
	• Evidence from a meta-analysis that incorporated quality ratings in the analysis
	Compelling non-experimental evidence, i.e., "all or none" rule developed by Center for
	Evidence Based Medicine at Oxford
	Supportive evidence from well-conducted randomized controlled trials that are adequately
	powered, including:
	• Evidence from a well-conducted trial at one or more institutions
	• Evidence from a meta-analysis that incorporated quality ratings in the analysis
В	Supportive evidence from well-conducted cohort studies
	• Evidence from a well-conducted prospective cohort study or registry
	• Evidence from a well-conducted meta-analysis of cohort studies
	Supportive evidence from a well-conducted case-control study
С	Supportive evidence from poorly controlled or uncontrolled studies

	• 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	
	Conflicting evidence with the weight of evidence supporting the recommendation	
Е	Expert consensus or clinical experience	

3. United States Preventative 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 <u>all</u> 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. Preventative 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, C5that no recommendation for or against the routine provision of the intervention can be made, and D5that 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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