Local Coverage Determination (LCD): Non-Covered Services (L35008)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	02101 - MAC A	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02102 - MAC B	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02201 - MAC A	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02202 - MAC B	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02301 - MAC A	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02302 - MAC B	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02401 - MAC A	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	02402 - MAC B	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	03101 - MAC A	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03102 - MAC B	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03201 - MAC A	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03202 - MAC B	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03301 - MAC A	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03302 - MAC B	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03401 - MAC A	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03402 - MAC B	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03501 - MAC A	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03502 - MAC B	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03601 - MAC A	J - F	Wyoming
Noridian Healthcare Solutions, LLC	A and B MAC	03602 - MAC B	J - F	Wyoming

LCD Information

Document Information

LCD ID
L35008

Original Effective Date
For services performed on or after 10/01/2015

LCD Title

Revision Effective Date

Non-Covered Services

For services performed on or after 12/01/2019

Proposed LCD in Comment Period
N/A

Revision Ending Date
N/A

Source Proposed LCD
N/A

Retirement Date
N/A

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Notice Period Start Date
N/A

Notice Period End Date
N/A

CMS National Coverage Policy

Title XVIII of the Social Security Act, section 1862 (a) (1) (A). This section allows coverage and payment for only those services that are considered to be medically reasonable and necessary.

Title XVIII of the Social Security Act, section 1833 (e). This section prohibits Medicare payment for any claim which

lacks the necessary information to process the claim.

Medicare Claims Processing Manual (CMS Pub. 100-04), Chapter 23, Section 30 A

Medicare Program Integrity Manual

Medicare National Coverage Determination Manual
230.14 - Ultrafiltration Monitor

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Medicare does not cover items and services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member. Section 1862 (a) (1) of the Social Security Act is the basis for denying payment for types of care, or specific items, services, or procedures that are not excluded by any other statutory clause and meet all technical requirements for coverage but are determined to be any of the following:

- Not generally accepted in the medical community as safe and effective in the setting and for the condition for which it is used.
- Not proven to be safe and effective based on peer review or scientific literature.
- Experimental.
- Not medically necessary in the particular case.
- Furnished at a level, duration or frequency that is not medically appropriate.
- Not furnished in accordance with accepted standards of medical practice.
  Or,
- Not furnished in a setting (such as inpatient care at a hospital or SNF, outpatient care through a hospital or physicians office or home care) appropriate to the patients medical needs and condition.
  To be considered medically necessary, items and services must have been established as safe and effective. That is, the items and services must be:
- Consistent with the symptoms or diagnosis of the illness or injury under treatment.
- Necessary and consistent with generally accepted professional medical standards (e.g., not experimental or investigational).
- Not furnished primarily for the convenience of the patient, the attending physician or other physician or supplier.
- Furnished at the most appropriate level that can be provided safely and effectively to the patient.
  Medicare is a defined benefit program; contractors sometimes have to decide whether a service fits one of the defined benefits categories. Services that this contractor considers non-covered because the service does not fit into a benefit category are also included on this list.
  A service or procedure on the national non-coverage list may be non-covered for a variety of reasons. It may be non-covered based on a specific exclusion contained in the Medicare law (for example, acupuncture) it may be viewed as not yet proven safe and effective and, therefore, not medically reasonable and necessary; or it may be a procedure that is always considered cosmetic in nature and is denied on that basis. The precise basis for a national decision to non-cover a procedure may be found in the references cited in this policy. These national non-covered services are listed in this LCD for informational purposes only.
  A service or procedure on the local list is always denied on the basis that Noridian does not believe it is ever medically reasonable and necessary. The Noridian list of LCD exclusions contains procedures that, for example, are:
- Experimental.
- Not proven safe and effective.

Or,

- Not approved by the FDA.
  Medical devices that are not approved for marketing by the Food and Drug Administration (FDA) are considered investigational by Medicare and are not considered reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve functioning of a malformed body member. Program payment, therefore, may not be made for medical procedures and services performed using devices that have not been approved for marketing by the FDA or for those not included in an FDA-approved investigational (IDE) trial.
  If a test, treatment or procedure is neither specifically covered nor excluded in Medicare law or guidelines, carriers must make a coverage determination that is based upon the general acceptance of the test, treatment or procedure by the professional medical community as an effective and proven treatment for the condition for which it is being used. Medicare will make payment only when a service is accepted as effective and proven. Some tests or services are obsolete and have been replaced by more advanced procedures. The tests or procedures may be paid only if the physician who performs them satisfactorily justifies the medical need for the procedure(s).
  "When processing a claim, carriers continue to determine if a service is reasonable and necessary to treat illness or injury. If a service is not reasonable and necessary to treat illness or injury for any reason (including lack of safety and efficacy because it is an experimental procedure, etc.), carriers consider the service noncovered notwithstanding the presence of a payment amount for the service in the Medicare fee schedule. The presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare. The nature of the status indicator in the database does not control coverage except where the status is N for noncovered."
  [Medicare Claims Processing Manual (CMS Pub. 100-04, Chapter 23, Section 30 A)]
  It is important to note that the fact that a new service or procedure has been issued a CPT code or is FDA approved <u>for a specific indication</u> does not, in itself, make the procedure medically reasonable and necessary. Noridian evaluates new services, procedures, drugs or technology and considers national and local policies before these new services may be considered Medicare covered services.
  This LCD contains listings of numerous non-covered services which have no specific CPT code. Adding difficulty to correct coding for such services is the fact that there are many where two or more specific unlisted codes could arguably be used to designate the service. Initial preparation of the LCD to cover every possible code use – and more importantly, maintenance of the LCD as code changes occur – is difficult if not impossible.
  Therefore, providers must bear in mind that **any** service that is described in any Noridian LCD as "non-covered" will remain non-covered no matter which CPT code is selected for billing. Since many of the unlisted codes, however, are also correctly used for billing of **covered** services, it is likely that prepay denial edits cannot be implemented into the claims processing computer system. Because of this, clearly non-covered services can in some instances be paid. Providers are reminded that these paid services will be subject to recoupment by Noridian, as well as other review contractors, including the Recovery Audit Contractors (RACs).
  Services that this contractor considers a component of another service and never separately billable or payable are also included here unless those services are already included in the mutually exclusive Correct Coding edits. For some services one or more of the Medicare payment systems (for example, the Physician Fee Schedule or the Outpatient Prospective Payment System) may indicate that the service is bundled or packaged or not paid for some other reason, in which case those indicators take precedence over the placement in this policy.
  This is not an all-inclusive list of services not covered or not paid separately by Medicare (see the Billing and Coding article).
  If you disagree with some aspects of a final LCD, you have the option of submitting a formal reconsideration to Noridian Medicare Part B. See <u>www.noridianmedicare.com</u> for the reconsideration process. This reconsideration must be accompanied by complete copies of relevant peer-reviewed literature that support the recommendation. Abstracts are not sufficient for this purpose. Keep in mind that no change will be made that will put the LCD in conflict with CMS regulations.
  Removal of a service from this policy does not imply that the service is always covered. The service must meet

Medicare coverage criteria and the documentation in the medical record must support the service as billed. Compliance with the provisions in this policy is subject to monitoring by post payment data analysis and subsequent medical review.

Summary of Evidence

N/A

Analysis of Evidence
(Rationale for Determination)

N/A

General Information

Associated Information

When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary under Section 1862(a)(1) of the Social Security Act.

This policy is subject to the reasonable and necessary guidelines and the limitation of liability provision.

This medical policy consolidates and replaces all previous policies and publications on this subject by Noridian and its predecessors for Medicare Part B.

Sources of Information

CMS Manual System Transmittal 1315; Change Request 5667, August 10, 2007

Policies from other states:

First Coast Services Option policy

TrailBlazer Health Enterprises, LLC policy

Current Procedural Terminology (CPT®), Professional Edition American Medical Association

Noridian Carrier Advisory Committee Members

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Bibliography

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
12/01/2019	R31	12/01/2019: At this time 21st Century Cures Act will apply to new and revised LCDs that restric requires comment and notice. This revision is not a restriction to the coverage. As required by CR 10901, all billing and coding information has been moved to the companion a linked to the LCD.
01/01/2019	R30	Effective 1/1/2019, this LCD is being revised to remove Category III CPT code 0402T from Grou 1/8/19 - At this time, 21st Century Cures Act will apply to new and revised LCDs that restrict co comment and notice. This revision is not a restriction to the coverage determination and therefo included in the LCD are applicable as noted in this policy.

01/01/2019	R29	The LCD revised to remove deleted CPT codes effective 1/1/2019.
		
		• Deleted CPT from Group 1:
		  • 0190T, 0195T, 0196T, 0337T, 0346T, 0359T, 0360T, 0361T, 0363T, 0364T, 0365T, 0369T, 0370T, 0371T, 0372T, 0374T, 0406T, 0407T and
		  • 0159T from group 2.
		• Description changed for the following codes:
		• 0335T – Insertion of sinus tarsi implant
		• 0362T – Behavior identification supporting assessment, each 15 minutes of technicians' ti patient, requiring the following components: administration by the physician or other qual professional who is on site; with the assistance of two or more technicians; for a patient w behavior; completion in an environment that is customized to the patient's behavior
		• 0373T – Adaptive behavior treatment with protocol modification, each 15 minutes of techn with a patient, requiring the following components: administration by the physician or oth professional who is on site; with the assistance of two or more technicians; for a patient w behavior; completion in an environment that is customized to the patient's behavior.
		
		At this time, 21st Century Cures Act will apply to new and revised LCDs that restrict coverage w and notice. This revision is not a restriction to the coverage determination and therefore, not all LCD are applicable as noted in this policy.

08/24/2018	R28	Effective 8/24/2018, this LCD is revised to remove CPT code 32998 from Group 1 of the LCD. At this time, 21st Century Cures Act will apply to new and revised LCDs that restrict coverage w and notice. This revision is not a restriction to the coverage determination and therefore, not all LCD are applicable as noted in this policy.
06/21/2018	R27	Effective 6/21/2018, this LCD is being revised to remove Category III CPT code 0254T from Gro

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		At this time, 21st Century Cures Act will apply to new and revised LCDs that restrict coverage w and notice. This revision is not a restriction to the coverage determination and therefore, not all LCD are applicable as noted in this policy.
05/24/2018	R26	Effective 5/24/2018, this LCD is being revised to remove Category III CPT code 0398T from Gro At this time, 21st Century Cures Act will apply to new and revised LCDs that restrict coverage w and notice. This revision is not a restriction to the coverage determination and therefore not all LCD are applicable as noted in this policy.
04/06/2018	R25	Effective 4/6/2018, the LCD is being revised to remove CPT code 84145 from Group I. 4/25/2018 - At this time, 21st Century Cures Act will apply to new and revised LCDs that restric requires comment and notice. This revision is not a restriction to the coverage determination an fields included in the LCD are applicable as noted in this policy.
01/01/2018	R24	Effective 01/01/2018, this LCD is revised to remove Category III CPT code 0449T from Group I. At this time, 21st Century Cures Act will apply to new and revised LCDs that restrict coverage w and notice. This revision is not a restriction to the coverage determination and therefore, not all LCD are applicable as noted in this policy.
01/01/2018	R23	LCD revised for the 2018 HCPCs/CPT updates. Effective 12/31/2017 the following codes will be deleted from Group 1: 0255T, 0293T, 0294T, 0299T, 0300T, 0301T, 0302T, 0303T, 0304T, 0305T, 0306T, 0310T, 034 The code description was changed for CPT 32998 from Group 1. At this time, 21st Century Cures Act will apply to new and revised LCDs that restrict coverage w and notice. This revision is not a restriction to the coverage determination and therefore not all LCD are applicable as noted in this policy.
10/27/2017	R22	This LCD is being revised effective 10/27/2017 to remove CPT code 43210 from Group 1. 10/17/2017 - At this time, 21st Century Cures Act will apply to new and revised LCDs that restri requires comment and notice. This revision is not a restriction to the coverage determination an fields included in the LCD are applicable as noted in this policy.

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
01/18/2017	R21	7/26/17 - Category III CPT code 0275T will be removed from the Non-Covered Services LCD du Evidence Development (CED) clinical trial guidelines found in National Coverage Determination (12/6/16 7/26/17 - At this time, 21st Century Cures Act will apply to new and revised LCDs that restrict c comment and notice. This revision is not a restriction to the coverage determination and therefo included in the LCD are applicable as noted in this policy.
01/18/2017	R20	04/18/2017 - Removal of Leadless Pacemaker Category III CPT codes 0387T - 0391T from Grou
01/01/2017	R19	Effective 01/01/2017 the description Decision DX UM is removed from Group I description of mis list.
01/01/2017	R18	LCD revised for the 2017 HCPCS/CPT codes: Added to Group I 43284, 43285, 0446T, 0447T, 0448T, 0449T, 0450T, 0451T, 0452T, 0453T, 0 0457T, 0458T, 0459T, 0460T, 0461T, 0462T, 0463T, 0464T, 0465T, 0466T, 0467T, 0468T. Effective 12/31/2016 the following codes have been deleted:0019T, 0169T, 0286T, 0287T, 0288 0292T, 0392T (replaced with 43284), 0393T (replaced with 43285).
08/08/2016	R17	The LCD is revised to remove 86352 from group 1, effective August 8, 2016.
07/01/2016	R16	The LCD is revised to add the following Category III CPT codes effective 7/1/2016: 0437T, 0438T, 0440T, 0441T, 0442T, 0439T, 0443T, 0444T, 0445T.
05/31/2016	R15	Transcranial stimulation for depression listed under Group I for unlisted procedures code descrip removed when this LCD was revised to remove CPT codes 90867, 90868 and 90869 from Group 4/1/2016 remains the same.
05/31/2016	R14	This policy is revised effective 05/31/2016 only to combine JFA L34886 into the JFB LCD so that contract numbers will have the same final MCD LCD number.

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
05/31/2016	R13	This LCD is revised to remove CPT codes 82172 and 83698 from group 1 effective 5/31/2016. A for CPT code 0281T removed from LCD with an effective date of 2/8/2016. The correct effective 2/07/2016 and not 2/8/2016.
04/01/2016	R12	This LCD is revised to remove CPT codes 90867, 90868 and 90869 from group 1 with an effectiv
02/08/2016	R11	The LCD is revised to remove CPT Code 0281T from Group 1 with an effective date of 2/8/2016.
01/11/2016	R10	The LCD is revised to remove 22856, 22858 and 22861 effective 1/11/2016.
01/01/2016	R9	The LCD is revised to add the following CPT Codes in Group 1: 43210, 0396T, 0397T, 0398T, 0400T, 0401T, 0402T, 0406T, 0407T, 0408T, 0409T, 0410T, 041 0414T, 0415T, 0416T, 0417T, 0418T, 0419T, 0420T, 0421T, 0422T, 0423T, 0424T, 0425T, 042 0429T, 0430T, 0431T, 0432T, 0433T, 0434T, 0435T, and 0436T. Group 2 – 93050, 0399T Group 3 - 0403T, 0405T. Effective date is 1/1/2016. 93050 added in group 2 to replace 0311T deleted 1/1/2016. Transoral Incisionless Fundoplication is removed from the miscellaneous procedure list. The proc 2016 and is added to group 1. The following CPT codes removed from this LCD because they were deleted effective 1/1/2016: 0103T, 0123T, 0223T, 0224T, 0225T, 0233T, 0240T, 0241T, 0243T, 0244T and 0311T.
12/01/2015	R8	Medialization Thyroplasty is removed from the policy listed in Group 1 of unlisted procedure cod and should be billed with CPT code 31588 effective December 1, 2015.

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
10/01/2015	R7	The LCD revised to add 0392T and 0393T to Group 1 and to remove CPT code 91112 from group
10/01/2015	R6	The CPT Code 0262T was removed from Group 1. Each claim for CPT Code 0262T will be reviewe basis.
10/01/2015	R5	The CPT Code 0262T was removed from Group 1 because the same code was also removed from effective 7/9/2015.
10/01/2015	R4	Revisions made to the following sections of the policy after the comment period ending 07/11/2 1. "Coverage Indications, Limitations and/or Medical Necessity" ? Medicare is a defined benefit program; contractors sometimes have to decide whether a servic benefits categories. Services that this contractor considers non-covered because the service doe category are also included on this list. ? Services that this contractor considers a component of another service and never separately b also included here unless those services are already included in the mutually exclusive Correct C services one or more of the Medicare payment systems (for example, the Physician Fee Schedul Prospective Payment System) may indicate that the service is bundled or packaged or not paid f which case those indicators take precedence over the placement in this policy. ? This is not an all-inclusive list of services not covered or not paid separately by Medicare. ? Removal of a service from this policy does not imply that the service is always covered. The se Medicare coverage criteria and the documentation in the medical record must support the servic 2. Group 1 - Removed Ova 1 Test, Prolaris® assay for clinical classification of prostate cancer pr 27416, 29866, 29867, 29868, 68399. Moved CPT codes 0378T, 0379T and 0380T to group 3. Ad 3. Group 3 - Removed 0199T, Added 0378T, 0379T and 0380T from Group 1. 4. Sources of Information and Basis for Decision - Added #29 to the list.
10/01/2015	R3	This LCD is revised to remove Group 4 for Non-covered products: Not Separately Payable as bio substitutes for the following HCPCS codes: Q4100, Q4104, Q4105, Q4108, Q4111, Q4112, Q411 Q4116, Q4117, Q4118, Q4119, Q4120, Q4122, Q4123, Q4125, Q4126, Q4127, Q4128, Q4129, Q4134, Q4135, Q4136 and Q4147.
10/01/2015	R2	The LCD was revised due to the Annual CPT code update effective 01/01/2015. The following codes are deleted from the LCD: 0092T, 0181T, 0199T, 0239T and 0334T for Grou The following codes are added to the LCD: 0357T, 0375T, 0376T, 0378T, 0379T, 0380T, 0381T, 0385T, 0386T, 0387T, 0388T, 0389T, 0390T, 0391T, 22858, 92145 (replaced 0181T), and 9370 0126T is moved from Group 1 to Group 2. Q4147 is moved from Group 2 to Group 4.

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
10/01/2015	R1	07/01/2014 - Codes 0347T, 0348T, 0349T, 0350T, 0351T, 0352T, 0353T, 0354T, 0355T, 0356T 0361T, 0362T, 0363T, 0364T, 0365T, 0366T, 0367T, 0368T, 0369T, 0370T, 0371T, 0372T, 037 the non-covered list per the new Category III CPT codes issued in the January release. 68399 ar removed.Q4147 was added to Group 2 paragraph codes,not separately payable. 03/01/2014 Prolonged Extracorporeal percutaneous transseptal assist device, codes 0075T and

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)
A55681 - Additional Information Required for Coverage and Pricing for Category III CPT® Codes
A57642 - Billing and Coding: Non-Covered Services

Related National Coverage Documents

N/A

Public Version(s)

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