## Contractor Information

<table>
<thead>
<tr>
<th>CONTRACTOR NAME</th>
<th>CONTRACT TYPE</th>
<th>CONTRACT NUMBER</th>
<th>JURISDICTION</th>
<th>STATE(S)</th>
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<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>02101 - MAC A</td>
<td>J - F</td>
<td>Alaska</td>
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<tr>
<td>Noridian Healthcare Solutions, LLC</td>
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<td>J - F</td>
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<td>Noridian Healthcare Solutions, LLC</td>
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<td>Noridian Healthcare Solutions, LLC</td>
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<td>J - F</td>
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</tbody>
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## LCD Information

### LCD ID
L35008

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

### LCD Title

### Revision Effective Date
Non-Covered Services

Proposed LCD in Comment Period
N/A

Source Proposed LCD
N/A

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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 for a specific indication 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 www.noridianmedicare.com 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


Noridian Carrier Advisory Committee Members


2. Boyan, Barbara D.,Schwartz, Zvi, Patterson, Thomas E., Muschler, George: Clinical use of platelet-rich plasma in


Bibliography

N/A

Revision History Information

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<table>
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<tr>
<th>REVISION HISTORY DATE</th>
<th>REVISION HISTORY NUMBER</th>
<th>REVISION HISTORY EXPLANATION</th>
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<tr>
<td>12/01/2019</td>
<td>R31</td>
<td>12/01/2019: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which 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 article and linked to the LCD.</td>
</tr>
<tr>
<td>01/01/2019</td>
<td>R30</td>
<td>Effective 1/1/2019, this LCD is being revised to remove Category III CPT code 0402T from Group 1. 1/8/19 - At this time, 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination and therefore, not all fields included in the LCD are applicable as noted in this policy.</td>
</tr>
<tr>
<td>01/01/2019</td>
<td>R29</td>
<td>The LCD revised to remove deleted CPT codes effective 1/1/2019. - Deleted CPT from Group 1: 0190T, 0195T, 0196T, 0337T, 0346T, 0359T, 0936T, 0361T, 0363T, 0364T, 0365T, 0366T, 0367T, 0368T, 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’ time face-to-face with a patient, requiring the following components: administration by the physician or other qualified health care professional who is on site; with the assistance of two or more technicians; for a patient who exhibits destructive behavior; completion in an environment that is customized to the patient’s behavior - 0373T – Adaptive behavior treatment with protocol modification, each 15 minutes of technicians’ time face-to-face with a patient, requiring the following components: administration by the physician or other qualified health care professional who is on site; with the assistance of two or more technicians; for a patient who exhibits destructive 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 which requires comment and notice. This revision is not a restriction to the coverage determination and therefore, not all fields included in the LCD are applicable as noted in this policy.</td>
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<tr>
<td>08/24/2018</td>
<td>R28</td>
<td>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 which requires comment and notice. This revision is not a restriction to the coverage determination and therefore, not all fields included in the LCD are applicable as noted in this policy.</td>
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<tr>
<td>06/21/2018</td>
<td>R27</td>
<td>Effective 6/21/2018, this LCD is being revised to remove Category III CPT code 0254T from Group 2. Creation of Uniform LCDs Within a MAC Jurisdiction</td>
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<td>05/24/2018</td>
<td>R26</td>
<td>Effective 5/24/2018, this LCD is being revised to remove Category III CPT code 0398T from Group I. At this time, 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination and therefore not all the fields included in the LCD are applicable as noted in this policy.</td>
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<tr>
<td>04/06/2018</td>
<td>R25</td>
<td>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 restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination and therefore not all the fields included in the LCD are applicable as noted in this policy.</td>
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<tr>
<td>01/01/2018</td>
<td>R24</td>
<td>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 which requires comment and notice. This revision is not a restriction to the coverage determination and therefore, not all the fields included in the LCD are applicable as noted in this policy.</td>
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<tr>
<td>01/01/2018</td>
<td>R23</td>
<td>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, 0340T, 34806, 93982 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 which requires comment and notice. This revision is not a restriction to the coverage determination and therefore not all the fields included in the LCD are applicable as noted in this policy.</td>
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<tr>
<td>10/27/2017</td>
<td>R22</td>
<td>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 restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination and therefore not all the fields included in the LCD are applicable as noted in this policy.</td>
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<td>01/18/2017</td>
<td>R21</td>
<td>7/26/17 - Category III CPT code 0275T will be removed from the Non-Covered Services LCD due to Evidence Development (CED) clinical trial guidelines found in National Coverage Determination (NCD) 150.13 effective 12/6/16. 7/26/17 - At this time, 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination and therefore not all the fields included in the LCD are applicable as noted in this policy.</td>
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<tr>
<td>01/18/2017</td>
<td>R20</td>
<td>04/18/2017 - Removal of Leadless Pacemaker Category III CPT codes 0387T - 0391T from Group I.</td>
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<tr>
<td>01/01/2017</td>
<td>R19</td>
<td>Effective 01/01/2017 the description Decision DX UM is removed from Group I description of miscellaneous procedures list.</td>
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<tr>
<td>01/01/2017</td>
<td>R18</td>
<td>LCD revised for the 2017 HCPCS/CPT codes: Added to Group I 43284, 43285, 0446T, 0447T, 0448T, 0449T, 0450T, 0451T, 0452T, 0453T, 0454T, 0455T, 0456T, 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, 0288T, 0289T, 0292T, 0392T (replaced with 43284), 0393T (replaced with 43285).</td>
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<tr>
<td>08/08/2016</td>
<td>R17</td>
<td>The LCD is revised to remove 86352 from group 1, effective August 8, 2016.</td>
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<tr>
<td>07/01/2016</td>
<td>R16</td>
<td>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.</td>
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<tr>
<td>05/31/2016</td>
<td>R15</td>
<td>Transcranial stimulation for depression listed under Group I for unlisted procedures code descriptions removed when this LCD was revised to remove CPT codes 90867, 90868 and 90869 from Group I. 4/1/2016 remains the same.</td>
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<tr>
<td>05/31/2016</td>
<td>R14</td>
<td>This policy is revised effective 05/31/2016 only to combine JFA L34886 into the JFB LCD so that both JFA and JFB contract numbers will have the same final MCD LCD number.</td>
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<tr>
<td>05/31/2016</td>
<td>R13</td>
<td>This LCD is revised to remove CPT codes 82172 and 83698 from group 1 effective 5/31/2016. Also a correction is made for CPT code 0281T removed from LCD with an effective date of 2/8/2016. The correct effective date should be 2/07/2016 and not 2/8/2016.</td>
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<tr>
<td>04/01/2016</td>
<td>R12</td>
<td>This LCD is revised to remove CPT codes 90867, 90868 and 90869 from group 1 with an effective date of 4/1/2016.</td>
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<tr>
<td>02/08/2016</td>
<td>R11</td>
<td>The LCD is revised to remove CPT Code 0281T from Group 1 with an effective date of 2/8/2016.</td>
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<td>01/11/2016</td>
<td>R10</td>
<td>The LCD is revised to remove 22856, 22858 and 22861 effective 1/11/2016.</td>
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<td>01/01/2016</td>
<td>R9</td>
<td>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, 0411T, 0412T, 0413T, 0414T, 0415T, 0416T, 0417T, 0418T, 0419T, 0420T, 0421T, 0422T, 0423T, 0424T, 0425T, 0426T, 0427T, 0428T, 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 procedure code is 43210 for 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.</td>
</tr>
<tr>
<td>12/01/2015</td>
<td>R8</td>
<td>Medialization Thyroplasty is removed from the policy listed in Group 1 of unlisted procedure codes and should be billed with CPT code 31588 effective December 1, 2015.</td>
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Created on 01/02/2020. Page 11 of 13
**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 1.

10/01/2015 R6  The CPT Code 0262T was removed from Group 1. Each claim for CPT Code 0262T will be reviewed on a case-by-case basis.

10/01/2015 R5  The CPT Code 0262T was removed from Group 1 because the same code was also removed from the ICD9 LCD copy effective 7/9/2015.

10/01/2015 R4  Revisions made to the following sections of the policy after the comment period ending 07/11/2014:

1. "Coverage Indications, Limitations and/or Medical Necessity"
   - 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.
   - 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.
   - 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.

2. Group 1 - Removed Ova 1 Test, Prolaris assay for clinical classification of prostate cancer prognosis, 27412, 27415, 27416, 29866, 29867, 29868, 68399. Moved CPT codes 0378T, 0379T and 0380T to group 3. Added 90869 and 0310T.

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 bioengineered skin substitutes for the following HCPCS codes: Q4100, Q4104, Q4105, Q4108, Q4111, Q4112, Q4113, Q4114, Q4115, Q4116, Q4117, Q4118, Q4119, Q4120, Q4122, Q4123, Q4125, Q4126, Q4127, Q4128, Q4129, Q4130, Q4132, Q4133, 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 Group 1.

The following codes are added to the LCD: 0357T, 0375T, 0376T, 0378T, 0379T, 0380T, 0381T, 0382T, 0383T, 0384T, 0385T, 0386T, 0387T, 0388T, 0389T, 0390T, 0391T, 22858, 92145 (replaced 0181T), and 93702 (replaced 0239T).

0126T is moved from Group 1 to Group 2.

Q4147 is moved from Group 2 to Group 4.
10/01/2015 R1 07/01/2014 - Codes 0347T, 0348T, 0349T, 0350T, 0351T, 0352T, 0353T, 0354T, 0355T, 0356T, 0357T, 0358T, 0359T, 0360T, 0361T, 0362T, 0363T, 0364T, 0365T, 0366T, 0367T, 0368T, 0369T, 0370T, 0371T, 0372T, 0373T, 0374T were added to the non-covered list per the new Category III CPT codes issued in the January release. 68399 and Q4147 was added to Group 2 paragraph codes, not separately payable.

03/01/2014 Prolonged Extracorporeal percutaneous transseptal assist device, codes 0075T and 0076T removed.