

Local Coverage Determination (LCD): Frequency of Hemodialysis (L37504)

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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

L37504

Original Effective Date

For services performed on or after 02/18/2019

LCD Title**Revision Effective Date**

Frequency of Hemodialysis

For services performed on or after 07/01/2019

Proposed LCD in Comment Period

N/A

Revision Ending Date

N/A

Source Proposed LCD

DL37504

Retirement Date

N/A

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Notice Period Start Date

01/03/2019

Notice Period End Date

02/17/2019

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CMS National Coverage Policy

This LCD supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for additional hemodialysis sessions. Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or supersede applicable

state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for additional hemodialysis sessions and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies may be found in the following Internet-Only Manuals (IOMs) published on the CMS Web site:

IOM Citations:

- CMS IOM Publication 100-01, *Medicare General Information, Eligibility and Entitlement Manual*
 - Chapter 1, Section 10: General Program Benefits.
 - Chapter 2, Section 10: Hospital Insurance Entitlement.
- CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 11, End Stage Renal Disease (ESRD).
- CMS IOM Publication 100-03, *Medicare National Coverage Determinations (NCD) Manual*, Chapter 1
 - Part 2, Section 110.10: Intravenous Iron Therapy; Section 110.15: Ultrafiltration, Hemoperfusion and Hemofiltration.
 - Part 4, Section 260.6: Dental Examination Prior to Kidney Transplantation.
- CMS IOM Publication 100-04, *Medicare Claims Processing Manual*, Chapter 8: Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims, all sections including Section 140 Monthly Capitation Payment Method for Physicians' Services Furnished to Patients on Maintenance Dialysis.
- CMS IOM Publication 100-05, *Medicare Secondary Payer Manual*, Chapter 2, Section 20: Medicare Secondary Payer Provisions for End Stage Renal Disease (ESRD) Beneficiaries.
- CMS IOM Publication 100-08, *Medicare Program Integrity Manual*, Chapter 13, Section 13.5.4: Reasonable and Necessary Provisions in LCDs.

Change Request References:

- Change Request 5039, Transmittal 1084, October 27, 2006: Line Item Billing Requirement for End Stage Renal Disease (ESRD) Claims.
- Change Request 9989, Transmittal 1849, May 12, 2017: Implementation of Modifier CG for Type of Bill 72X.
- Change Request 10901, Local Coverage Determinations (LCDs)

Social Security Act (Title XVIII) Standard References:

- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.

Federal Register References:

- 42 CFR, Chapter IV, Subchapter G, Part 494, Subpart C,
 - Section 494.80 Condition: Patient assessment.
 - Section 494.90 Condition: Patient plan of care.
- CMS Final Rule CMS-1651-F published November 4, 2016

Note: *Italicized font* represents CMS manual titles, journal titles and/or CMS national NCD language/wording copied directly from CMS Manuals or CMS Transmittals. Contractors are prohibited from changing national NCD language/wording.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Notice: It is not appropriate to bill Medicare for services that are not covered (as described by this entire LCD) as if they are covered. When billing for non-covered services, use the appropriate modifier.

Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.

History/Background and/or General Information

According to the Kidney Disease Outcomes Quality Initiative (KDOQI) Practice Guideline for Hemodialysis Adequacy: 2015 update¹, over 400,000 patients are currently treated with hemodialysis (HD) in the United States, with Medicare spending approaching \$90,000 per year of care in 2012. They note mortality rates remain higher than age-matched individuals in the general population. They also experience an average of 2 hospitalizations per year.

The KDOQI 2015¹ Update states the following: Attempts to improve outcomes have included initiating dialysis at higher glomerular filtration rates (GFRs), increasing dialysis frequency and/or duration, using newer membranes, and employing supplemental or alternative hemofiltration. Efforts to increase the dose of dialysis administered 3 times weekly have not improved survival, indicating that something else needs to be addressed.

This guideline was also cited in the most recent CMS Final Rule CMS-1651-F published November 4, 2016.

Covered Indications

1. Metabolic conditions (acidosis, hyperkalemia, hyperphosphatemia)
2. Fluid positive status not controlled with routine dialysis
3. Pregnancy
4. Heart Failure
5. Pericarditis
6. Incomplete dialysis secondary to hypotension or access issues

Limitations The following are considered not reasonable and necessary and therefore will be denied as not medically justified for payments.

1. Sessions furnished in excess of 3 sessions per week are not considered reasonable and necessary unless fully supported in the medical documentation as detailed in this policy
2. Planned inadequate or short dialysis
3. Sessions performed for convenience of patient or staff

There are documentation requirements in this LCD which if not followed will generate denials. Please refer to the Documentation Requirements section below.

While there are no set frequency limitations for these services, continued use of additional sessions by a given provider or for a given beneficiary or unusual patterns of billing, verification of need for services may generate reviews. Please refer to the Utilization Guidelines section below.

For coding guidelines, please refer to the companion, A55676-Billing and Coding: Frequency of Hemodialysis.

Notice: Services performed for any given diagnosis must meet all of the indications and limitations stated in this policy and associated A55676, Coding for Hemodialysis Sessions; the general requirements for medical necessity as stated in CMS payment policy manuals; any and all existing CMS National Coverage Determinations; and all Medicare payment rules.

The redetermination process may be utilized for consideration of services performed outside of the reasonable and necessary requirements in this LCD.

HD at 3 times (3X) per week is noted to be 'conventional' treatment. Conventional HD remains the most common treatment modality for end stage renal disease (ESRD) worldwide and is usually performed for 3 to 5 hours, 3 days per week. CMS established payment for hemodialysis based on conventional treatment.

Hence, Medicare reimburses HD treatments 3 times per week (13/14 sessions per month depending on length of month). In CMS-1651-F (November 4, 2016), CMS outlines the process for medical justification aspect of the overall requirements of being reasonable and necessary for additional treatment payments.

This LCD sets out medical conditions likely to meet reasonable and necessary requirements for additional payments.

ESRD Facilities establish parameters for treatment of any given patient through a Patient Plan of Care (POC). It is defined in the Conditions of Coverage for ESRD Services 42 CFR 494.90. Among other items, the POC developed by the Interdisciplinary Team must provide the necessary care and services to manage the patient's volume status; and achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis.

The prescription for chronic hemodialysis therapies includes the type of dialysis access, the type and amount of anticoagulant to be employed, blood flow rates, dialysate flow rate, ultrafiltration rate, dialysate temperature, type of dialysate (acetate versus bicarbonate) and composition of the electrolytes in the dialysate, size of hemodialyzer (surface area) and composition of the dialyzer membrane (conventional versus high flux), duration and frequency of treatments, the type and frequency of measuring indices of clearance, and intradialytic medications to be administered.

Those treatment sessions furnished to the beneficiary are paid by Medicare as 3X per week. If more than three sessions per week are furnished, such as 4-6 sessions per week, Medicare will pay the 3X per week amount unless there is a covered indication, appropriate use of the KX modifier occurs, and it is supported by medical documentation. Refer to the Local Coverage Article A55676, Billing and Coding: Frequency of Hemodialysis for more information on appropriate use of the KX modifier.

However, on occasion, acute, and occasionally chronic, conditions may require additional sessions during the month. These may be considered for additional payment. The associated Local Coverage Article A55676, Billing and Coding: Frequency of Hemodialysis, provides a list of diagnoses felt to be consistent with such clinical conditions that could establish reasonable and necessary requirements for payment. Use of these diagnoses should be verified in the medical records to support any payment made.

Clinical conditions not seen listed in this policy may still be appropriate to allow payment. However, these claims may require additional review through the appeals process.

Medicare will monitor the frequency of additional sessions which may trigger Medical Review.

The POC reassessment is noted in 42 CFR 494.80(d).

Please note the Plan of Care does not establish medical necessity by itself and will need to be supported by other medical documentation as outlined in the documentation requirements below.

Repeated need for additional dialysis sessions is expected to be addressed in the medical documentation and addressed in the subsequent POC, including attempts to correct any issues, (See medical documentation requirements below).

This LCD establishes documentation requirements as listed in the appropriate section below.

Summary of Evidence

KDOQI Clinical Practice Guideline for Hemodialysis Adequacy: 2015 Update¹, Guideline 4.1.1 states to "Consider additional hemodialysis sessions or longer hemodialysis treatment times for patients with large weight gains, high ultrafiltration rates, poorly controlled blood pressure, difficulty achieving dry weight, or poor metabolic control (such as hyperphosphatemia, metabolic acidosis, and/or hyperkalemia)." This specific recommendation was 'Not Graded' in the Guidelines but based on expert opinions. However, these guidelines are determined by a panel of experts and are felt to have a STRONG level of evidence to follow.

While uncontrolled hypertension is noted to be an indication for additional dialysis frequency, the included diagnoses are felt to be adequate for the condition in lieu of an available ICD-10 diagnosis.

The Kidney Disease: Improving Global Outcomes (KDIGO) Guidelines² for the evaluation and management of chronic kidney disease (CKD) address the many facets of CKD. The guidelines discuss the management variables that may affect CKD. Indications are supportive of guidelines above.

The 2018 Seminars in Dialysis article, "When is more frequent hemodialysis beneficial?", Suri and Kliger³ discuss the unresolved issue pertaining to frequency of dialysis. They review 3 randomized trials, 15 comparative cohort studies and some case series for recommendations and adverse events related to increased frequency of dialysis. They note effect on mortality remains controversial with conflicting results. More frequent dialysis is noted as being associated with vascular access site problems. Recommendations for increased frequency of dialysis include pregnant women, patients who are unable to obtain a dry weight on 3X per week regimen and for minimal urine output patients with left ventricular hypertrophy.

National experts were also contacted for input during development of this policy.

Analysis of Evidence (Rationale for Determination)

Based on KDOQI Practice Guidelines as well as KDIGO Guidelines, and the Suri and Kliger article, the listed conditions in the LCD may meet reasonable and necessary requirements for additional payments.

Based on local collaborative data, Medicare contractors expect the list of diagnoses in the associated Article A55676: Billing and Coding: Frequency of Hemodialysis would represent the great majority of claims for which additional payments may occur.

Facilities with sites in multiple states should be able to submit claims in a unified approach.

However, this LCD would not be the appropriate approach to change the payment methodology by CMS and reconsiderations to this LCD to potentially try to change the CMS payment process will be denied as invalid reconsideration to this LCD.

Coding Information:

Please refer to the Local Coverage Article, A55676 Billing and Coding: Frequency of Hemodialysis for all billing and coding information.

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

| CODE | DESCRIPTION |
|------|----------------|
| 999x | Not Applicable |

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

| CODE | DESCRIPTION |
|------|---|
| 0999 | Patient Convenience Items - Other Convenience Items |

CPT/HCPCS Codes

Group 1 Paragraph:

N/A

Group 1 Codes:

| CODE | DESCRIPTION |
|-------|----------------|
| XX000 | Not Applicable |

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph:

N/A

Group 1 Codes:

| ICD-10 CODE | DESCRIPTION |
|-------------|----------------|
| XX000 | Not Applicable |

ICD-10 Codes that DO NOT Support Medical Necessity

Group 1 Paragraph:

N/A

Group 1 Codes:

| ICD-10 CODE | DESCRIPTION |
|-------------|----------------|
| XX000 | Not Applicable |

Additional ICD-10 Information

General Information

Associated Information

Documentation Requirements

1. All documentation must be maintained in the patient's medical record and made available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service[s]). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
3. The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed.
4. The medical record documentation must support the medical necessity of the services as directed in this policy.
5. The medical records documentation should include the order from the prescribing physician for the additional sessions. This should be available for each and every additional session outside the usual 13/14 treatments per month with the CG modifier appended as well as those described in this LCD with the KX modifier appended. Should the records not show the order and evaluation leading to additional sessions denials will occur.
6. Documentation should be available on request and may include: the updated Plan of Care, documents from recent hospital care, office visits, dialysis progress notes, or Monthly Capitation Payment (MCP) visits reflecting the clinician's assessment and changes as indicated. Lack of this documentation will lead to denials.

Utilization Guidelines

In accordance with CMS Ruling 95-1 (V), utilization of these services should be consistent with locally acceptable standards of practice.

With continued utilization of additional sessions by a specific provider generally, or for a given beneficiary, providers should expect medical review of medical records by contractors.

Sources of Information

Contractor is not responsible for the continued viability of websites listed.

Novitas Solutions, Inc., L35014 - Frequency of Hemodialysis

Other Contractor's Policies:

First Coast Service Options, L33970 - Frequency of Hemodialysis

Palmetto GBA, L34575 - Frequency of Hemodialysis

Contractor Medical Director ESRD Workgroup

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Revision History Information

| REVISION HISTORY DATE | REVISION HISTORY NUMBER | REVISION HISTORY EXPLANATION | REASON(S) FOR CHANGE |
|-----------------------|-------------------------|---|---|
| 07/01/2019 | R2 | LCD revised and published 07/04/2019 effective for dates of service on and after 07/01/2019 consistent with Change Request 10901 to remove language from CMS Internet Only Manuals (IOMs) and/or regulations and list applicable manual/regulation reference and to remove all CPT and ICD-10 diagnosis codes. IOM references have been updated and all codes have been placed in the companion Local Coverage Article A55676, Billing and Coding: Frequency of Hemodialysis. There will not be a lapse in coverage and there has been no change to the coverage content in this LCD. | <ul style="list-style-type: none"> Other (Changes in response to CMS Change Request) |
| 03/01/2019 | R1 | This LCD is revised to change the effective date of the LCD from 2/18/19 to 3/1/2019. The effective date applies to dates of service, not to claim submission dates. | <ul style="list-style-type: none"> Other (The LCD effective date of 2/18/2019 is changed to 3/1/2019.) |

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A55676 - Billing and Coding: Frequency of Hemodialysis

A56241 - Response to Comments: Frequency of Hemodialysis

LCD(s)

DL37504 - Frequency of Hemodialysis

Related National Coverage Documents

NCD(s)

260.6 - Dental Examination Prior to Kidney Transplantation

110.10 - Intravenous Iron Therapy

110.15 - Ultrafiltration, Hemoperfusion and Hemofiltration

Public Version(s)

Updated on 06/28/2019 with effective dates 07/01/2019 - N/A

Keywords

- dialysis
- kidney disease
- end stage renal disease
- Frequency of Hemodialysis
- KDOQI
- ESRD
- 90999