

10-144 Chapter 101
MAINECARE BENEFITS MANUAL
CHAPTER II

SECTION 7

FREE-STANDING DIALYSIS SERVICES

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7.01 DEFINITIONS

Definitions for the purposes of this Section are as follows:

- 7.01-1 **Continuous Ambulatory Peritoneal Dialysis (CAPD)** is a form of dialysis in which dialysate drains into and out of the peritoneal cavity by gravity several times a day. This process does not require a machine; the process uses gravity to fill and empty the abdomen. A typical prescription for CAPD requires three or four exchanges during the day and one long (usually eight to ten hours) overnight exchange as the patient sleeps.
- 7.01-2 **Continuous Cycling-Assisted Peritoneal Dialysis (CCPD)** is a form of dialysis that uses a machine to fill and empty the abdomen three to five times during the night while the person sleeps. In the morning, the CCPD patient performs one exchange with a dwell time that lasts the entire day. Sometimes one additional exchange is done in the mid-afternoon to increase the amount of waste removed and to prevent excessive absorption of fluid.
- 7.01-3 **Dialysis** means the process of cleaning the blood and removing excess fluid artificially with special equipment when the kidneys have failed. Kidney dialysis is used to substitute for the function of damaged or absent kidneys. The two types of dialysis that are in common use are hemodialysis and peritoneal dialysis.
- 7.01-4 **End Stage Renal Disease (ESRD)** means that stage of kidney impairment that appears irreversible and permanent, cannot be controlled by conservative management alone, and requires a regular course of dialysis or kidney transplantation to maintain life.
- 7.01-5 **End Stage Renal Disease Services** are outpatient maintenance services provided by a free-standing ESRD facility or hospital-based renal dialysis center.
- 7.01-6 **Hemodialysis** is treatment for kidney failure in which the blood passes through a dialyzer to remove wastes and water. In this procedure, a patient typically spends approximately six hours, two to three times a week connected to a dialysis machine. This machine filters out unwanted wastes from a continuous flow of blood through a semipermeable membrane that is immersed in a special dialysis solution.
- 7.01-7 **Home Dialysis** means dialysis performed at home by an ESRD patient or caregiver who has completed an appropriate course of training consistent with federal guidelines contained in 42 CFR 494.100(a).
- 7.01-8 **Nocturnal Intermittent Peritoneal Dialysis (NIPD)** is similar to CCPD, except that the number of overnight exchanges is greater (six or more), and the patient does not perform an exchange during the day. NIPD is usually reserved for patients with a peritoneum that is able to transport waste products very rapidly, or for patients who still have substantial residual (remaining) kidney function.

7.01 DEFINITIONS (Cont'd)

7.01-9 **Peritoneal Dialysis** is a method of dialysis for patients with kidney failure in which fluids are pumped into the abdomen resulting in the removal of wastes from the blood. Peritoneal dialysis can be done in the home as opposed to hemodialysis, which must be done at a hospital or clinic.

7.01-10 **Renal Dialysis Facility** means an entity that is approved and licensed to provide outpatient maintenance dialysis services, or home dialysis training and support services, or both. A dialysis facility may be an independent or hospital-based unit; however, this chapter pertains only to independent, free-standing entities, which include self-care dialysis units that furnish only self-dialysis services. A dialysis facility shall provide outpatient dialysis services that include, at a minimum, hemodialysis, self-assisted dialysis services, self-dialysis services, laboratory services, and self-dialysis support services.

7.02 ELIGIBILITY FOR CARE

Members must meet the financial eligibility criteria as set forth in 10-144, Chapter 332, MaineCare Eligibility Manual. Some members may have restrictions on the type and amount of services they are eligible to receive. Providers are responsible for verifying a member's eligibility for MaineCare, as described in the MaineCare Benefit Manual, Chapter I, prior to providing services.

7.03 DURATION OF CARE

Each eligible member may receive covered services that are medically necessary within the limitations of this section. The Department of Health and Human Services (The Department) reserves the right to request additional information to evaluate medical necessity and review utilization of services. The Department may also require prior authorization (PA) for some services.

A member is eligible for as many MaineCare covered services as are specified in his or her individual plan of care. Beginning and end dates of a member's medical eligibility determination period correspond to the beginning and end dates for MaineCare coverage of the plan of care authorized by the provider or the Department.

7.04 COVERED SERVICES

For members who are establishing Medicare eligibility, MaineCare will cover renal dialysis services for the first three months of dialysis pending the establishment of Medicare eligibility. Medicare becomes the primary reimbursement source for all individuals who meet Medicare eligibility criteria. Dialysis providers must assist MaineCare members in applying for and pursuing final Medicare eligibility determinations. For those MaineCare members who are not Medicare eligible, MaineCare will continue to be the payer of last resort for dialysis services.

7.04 COVERED SERVICES (Cont'd)

- A. Renal Dialysis. Medically necessary renal dialysis services for eligible MaineCare members are covered under this section. Renal dialysis includes services, supplies, and routine laboratory tests as specified in Section 7.05.
- B. Prescribed Drugs. MaineCare reimburses dialysis clinics for prescribed drugs as specified in Section 7.05.
- C. Training for Home Dialysis. MaineCare reimburses for home dialysis training, including self-dialysis (hemodialysis, nocturnal intermittent peritoneal disease, and continuous cycling peritoneal dialysis) and continuous ambulatory peritoneal dialysis training only where the MaineCare member attends such training at the clinic site.

To facilitate coordination of benefits, the Department will follow Medicare coverage policies and claims submission requirements, as appropriate.

7.05 LIMITATIONS

MaineCare reimburses free-standing dialysis services as composite or non-composite services, patterned after the Medicare Policy Benefits Manual, Chapter 11: <http://www.cms.hhs.gov/manuals/Downloads/bp102c11.pdf> and any successor documents. This reference details drugs and laboratory tests considered composite and non-composite and the expected frequency for each dialysis method. MaineCare will only reimburse home-based dialysis by the composite methodology.

The following limitations apply for all services under this Section:

1. Composite reimbursement covers all routine personnel, drugs, laboratory tests, supplies and services associated with routine dialysis.
2. Non-composite or non-routine dialysis items or services as defined by Medicare include selected drugs, laboratory tests, blood and supplies that may be billed according to requirements in other sections of MaineCare policy, but on the same bill as the services included in the composite package.
3. Frequency of services must be consistent with the Medicare Policy Benefits Manual, Chapter 11 – Section 30.1.
4. Other drugs- MaineCare covers certain other drugs, such as epoetin alfa, outside of the composite rate when documented as medically necessary in relation to dialysis.
5. Medicare Part D- MaineCare will not cover drugs covered by Medicare Part D for those members who are eligible for Medicare Part D. The Department may automatically enroll such eligible MaineCare members without creditable coverage into Medicare Part D, and act as an authorized agent on their behalf. The Department will reimburse

7.05 LIMITATIONS (Cont'd)

Medicare Part D Excluded Drugs for members dually eligible for Medicare Part D when those drugs are otherwise covered by MaineCare.

7.06 NON-COVERED SERVICES

Please refer to the MaineCare Benefits Manual, Chapter I, General Administrative Policies and Procedures, for a general listing of non-covered services and associated definitions that are applicable to all Sections of the MaineCare Benefits Manual. In general, non-covered services include those items or services that are not medically necessary for the diagnosis and treatment of end stage renal disease (ESRD).

7.06-1 Physician Services

Physician professional services associated with dialysis are not included in the composite rate. Physician services are billable separately under Section 90 of the MaineCare Benefit Manual.

7.06-2 Missed Appointments

MaineCare will not reimburse missed appointments.

7.07 POLICIES AND PROCEDURES

7.07-1 Provider Eligibility

A free-standing dialysis center must be a MaineCare provider on the date of service in order to be eligible for reimbursement.

In-State Providers: To be eligible for participation as a MaineCare provider, a free-standing dialysis center must be:

1. located and doing business in the State of Maine (out-of-state providers within fifteen (15) miles of the Maine/New Hampshire border and within five (5) miles of the Maine/Canada border are treated the same as Maine providers in all aspects of policy requirements, including enrollment, rates of reimbursement, and payment methodologies);
2. certified by Medicare and providing services to the standards of a Medicare provider as provided in 42 CFR Part 494;
3. licensed as an out-of-hospital dialysis unit by the Maine Center for Disease Control and Prevention;
4. in compliance with all applicable federal, state and local laws and regulations and;

7.07 POLICIES AND PROCEDURES (Cont'd)

5. enrolled separately for facilities with multiple sites with the same owner/director.

7.07-2 Medicare Eligibility

Dialysis providers must assist MaineCare members in applying for and pursuing final Medicare eligibility determinations. If the Social Security Administration determines that an individual is not eligible for Medicare, documentation must be attached to the next MaineCare dialysis claim form.

7.07-3 Member Records

Providers must maintain written member records for all services, in chronological order. All member records must contain the following general categories of information:

- A. Member's name, address, birth date and MaineCare number
- B. The members file must include documentation supporting the following:
 1. timely assessment and reassessment (at least annually or more frequently as indicated) of the needs of the patient by the dialysis facility's interdisciplinary team. The interdisciplinary team should consist of, at a minimum, the patient or patient's designee, a registered nurse, a physician treating the patient for ESRD, a social worker and a dietician. The assessments must be completed within the later of 30 calendar days or 13 outpatient hemodialysis sessions after the member's first dialysis treatment;
 2. whether the patient is treated with a reprocessed hemodialyzer;
 3. establishment of a personalized plan of care and treatment and expectations for care based on current clinical standards;
 4. the care and services provided;
 5. the patient was fully informed of the results of the assessment regarding their suitability for transplantation and home dialysis;
 6. Signed consent forms, referral information and authentication of diagnosis;
 7. Member's medical, nursing and social history;
 8. Reports of physician examinations;
 9. Diagnostic and therapeutic orders;
 10. Observations and progress notes;

7.07 POLICIES AND PROCEDURES (Cont'd.)

11. Reports of treatments and clinical findings;
12. Reports of laboratory and other diagnostic tests and procedures;
13. Discharge summary including final diagnosis and prognosis;
14. Full account of any unusual condition or unexpected event.

7.07-4 Quality Assurance

The Department will conduct periodic review of cases to assure quality and appropriateness of care in accordance with the quality assurance (QA) protocols established by the Department consistent with federal Quality Assurance and Process Improvement (QAPI) requirements found at 42 CFR § 494.110.

Reviews will be in writing, signed and dated by the reviewers, and included in the clinical record.

The Department permits QA documentation to be kept in a separate and distinct file parallel to the clinical record.

7.07-5 Program Integrity (PI)

All providers are subject to the Department's Program Integrity activities. Refer to the MaineCare Benefits Manual, Chapter I, General Administrative Policies and Procedures for rules governing these functions.

7.08 REIMBURSEMENT

- A. The amount of payment for services rendered by a dialysis center shall be the facility composite rate. Medically necessary items or services that are not included in the composite rate may be billed and reimbursed in accordance with other sections of MaineCare policy (e.g., laboratory services, pharmacy services, physician services, etc.); however, non-composite items or services must be documented on the same claim form as the composite services.
- B. In accordance with Chapter I of the MaineCare Benefits Manual, it is the responsibility of the provider to seek payment from any other resources that are available for payment of the rendered service prior to billing the MaineCare Program.

7.09 BILLING INSTRUCTIONS

All of the following conditions must be met for provider reimbursement under this section.

- A. Providers must use the Department's approved billing form, in accordance with the Department's billing instructions available at http://www.maine.gov/dhhs/oms/providerfiles/billing_instructions.html
- B. Providers must bill dialysis services on a monthly basis for each member. All services provided during the same month must be submitted on the same claim form for MaineCare reimbursement.
- C. Providers must document appropriate and current diagnostic codes. These codes must accurately describe the clinical diagnosis of members receiving medically necessary treatment.
- D. In order to receive full MaineCare reimbursement for claims submitted for a service that is defined as an exemption to Chapter I, refer to the billing instructions distributed by the Department in Chapter I, General Administrative Policies and Procedures.
- E. Providers must provide all necessary services that are covered under the facility composite rate. Failure to provide an item or service covered under the composite rate will result in non-payment of the composite rate for that service.