

Clinical Policy: Hospice Services

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Effective Date: 01/18

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Coding Implications
Revision Log

Description

Hospice is a coordinated, integrated program developed by a multidisciplinary team of professionals to provide end-of-life care primarily focused on relieving pain and symptoms specifically related to the terminal diagnosis of members/enrollees with a life expectancy of six months or less. This policy describes the medical necessity criteria for hospice services.

Policy

It is the policy of Pennsylvania Health and Wellness® (PHW) that hospice is considered **medically necessary** when the *requirements in Criteria sections I, II, and III are met*:

- I. The Required Documentation has been submitted, and
- II. The member/enrollee meets one of the severity of illness criterion
 - A. Cancer, or
 - **B.** ALS, or
 - C. Heart Disease, or
 - D. Pulmonary Disease, or
 - E. Dementia, or
 - F. HIV, or
 - G. Liver Failure, or
 - H. Acute or Chronic Renal Failure, or
 - I. Stroke, or
 - J. Coma, or
 - **K.** Non-Disease Specific Decline in Clinical Status (for a member/enrollee not meeting any of the above disease specific criteria, A-J)
- **III.** The requested <u>intensity of service</u> is appropriate
 - A. Routine Hospice Home Care, or
 - B. Continuous Hospice Home Care, or
 - C. Inpatient Respite Hospice Care, or
 - **D.** General Inpatient, Short Term (non-respite) Hospice Care.

Note: Hospice room and board (long term care/nursing home) coverage is based on the Benefit Plan Contract.

It is the policy of PHW that hospice is considered **not medically necessary** when requested for the circumstances listed in Criteria section IV.

Criteria

I. Required Documentation

A. Documentation of hospice medical director certification of hospice appropriateness for the initial 90 day certification period.



- 1. The written certification must identify the terminal illness diagnosis that prompted the member/enrollee to seek hospice care, includes a statement that the member's/enrollee's life expectancy is six months or less if the terminal diagnosis runs its normal course; details specific clinical findings supporting a life expectancy of 6 months or less; and
- 2. The documentation also includes a hospice election statement signed by the member/enrollee or the member's/enrollee's healthcare proxy stating they understand the nature of hospice care; and

II. Severity of Illness

The presence of significant comorbidities should be considered, when using these criteria to determine hospice appropriateness. Note, however, there are exceptions to the below and combinations of disease state that may preclude these comorbidities from being individually applied as a basis for denial of hospice services. Exceptions to the below and combination of disease states will be considered on a case by case bases regarding denial of hospice services. Denials will require medical director review.

A. *Cancer* – meets 1, 2, and 3:

- 1. Palliative performance scale (PPS) (Appendix A) or Karnofsky performance status scale (KPS) (Appendix B) score decreased to < 70%; and
- 2. Dependence for at least 2 ADLs (i.e. ambulation, continence, transfers, dressing, feeding, bathing); and
- 3. Disease status is one of the following:
 - a. Metastatic cancer at presentation, deferring therapy, or
 - b. Progression to metastatic disease with decline despite therapy or deferring therapy, or
 - c. Brain, pancreatic, or small cell lung cancer.

B. ALS (Amyotrophic Lateral Sclerosis)—meets 1, 2, and 3:

- 1. PPS (Appendix A) or KPS (Appendix B) score decreased to < 70%; and
- 2. Dependence for at least 2 ADLs (i.e. ambulation, continence, transfers, dressing, feeding, bathing); and
- 3. Disease status is one of the following:
 - Signs or symptoms of impaired respiratory function, not electing tracheostomy or invasive ventilation, and forced vital capacity (FVC) < 30% (if results available);
 - b. Rapid progression with critical nutritional impairment indicated by at least 5% loss of body weight (with or without tube feeding), or
 - c. Rapid progression with other life-threatening complications (sepsis, recurrent aspiration, pyelonephritis, stage 3-4 decubiti).

C. Heart Disease – meets 1, 2, and either 3 or 4:

- 1. PPS (Appendix A) or KPS (Appendix B) score decreased to < 70%; and
- 2. Dependence for at least 2 ADLs (i.e. ambulation, continence, transfers, dressing, feeding, bathing); and
- 3. Disease status is one of the following:



- a. Congestive Heart Failure (CHF), both of the following:
 - i. Symptomatic at rest (NYHA Class IV), with ejection fraction (EF) < 20% (if results available), and
 - ii. Presently optimally treated with diuretics and vasodilators or has failed therapy with IV inotropes; or
- b. Coronary Artery Disease (CAD), all of the following:
 - i. Elderly member/enrollee with intractable angina who is not a candidate for coronary revascularization, and
 - ii. No longer responding well to nitrates, beta- and calcium-channel blockers and other appropriate medications, and
 - iii. Not a candidate for cardiac transplant.
- **D.** *Pulmonary Disease* has fixed obstructive disease OR restrictive disease and meets ALL of the following:
 - 1. PPS (Appendix A) or KPS (Appendix B) score decreased to < 70%; and
 - 2. Dependence for at least 2 ADLs (i.e. ambulation, continence, transfers, dressing, feeding, bathing); and
 - 3. Severity, all
 - a. Disabling symptoms at rest or with minimal exertion, and
 - b. Diminished functional capacity, i.e., bed-to-chair existence, and
 - c. Forced expiratory volume in 1 second (FEV1) <30% predicted; and
 - 4. Progressiveness, both
 - a. Two ED visits in prior six months or one hospitalization in last year for pulmonary infection for respiratory failure with intubation or BiPAP (bi-level positive airway pressure), and
 - b. member/enrollee states they do not want to be intubated; and
 - 5. Partial pressure of oxygen in arterial blood (PaO2) ≤ 55 mmHg or arterial oxygen saturation (SaO2) ≤ 88% at rest on room air; or partial pressure of carbon dioxide (PaCO2) ≥ 50 mmHg.
- **E.** *Dementia* meets ALL of the following:
 - 1. Increasing severity indicated by FAST (Appendix C) stage 7 or beyond; and
 - 2. Increasing medical complications indicated by one of the following in the past 12 months:
 - a. Aspiration pneumonia, or
 - b. Pyelonephritis, or
 - c. Multiple stage 3-4 decubiti, or
 - d. Fever recurrent after a course of antibiotics, or
 - e. Weight loss > 10% over six months or albumin <2.5 g/dl
 - f. Septicemia
- **F.** *HIV* meets ALL of the following:
 - 1. CD4+ (T-cell) count < 25 or viral load > 100,000 copies/ml; and
 - 2. PPS or KPS score < 50%; and
 - 3. At least one of the following AIDS-related conditions:
 - a. Central nervous system or poorly responsive systemic lymphoma, or

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- b. Wasting: loss of > 33% of lean body mass, or
- c. Mycobacterium avium complex (MAC) bacteremia, or
- d. Progressive multifocal leukoencephalopathy (PML), or
- e. Refractory visceral Kaposi's sarcoma (KS), or
- f. Renal failure in the absence of dialysis, or
- g. Refractory cryptosporidium infection, or
- h. Refractory toxoplasmosis.

G. *Liver Failure* – meets ALL of the following:

- 1. PPS (Appendix A) or KPS (Appendix B) score decreased to < 70%; and
- 2. Dependence for at least 2 ADLs (i.e. ambulation, continence, transfers, dressing, feeding, bathing); and
- 3. Member/Enrollee has end-stage liver disease and is not on the transplant list; and
- 4. PT > 5 seconds or INR > 1.5; and
- 5. Albumin < 2.5 gm/l; and
- 6. And at least one of the following:
 - a. Recurrent bleeding esophageal varices despite therapy, or
 - b. Refractory ascites, or
 - c. Episode of spontaneous bacterial peritonitis, or
 - d. Hepatorenal syndrome, or
 - e. Hepatic encephalopathy.

H. *Acute or Chronic Renal Failure* – meets ALL of the following:

- 1. PPS (Appendix A) or KPS (Appendix B) score decreased to < 70%; and
- 2. Dependence for at least 2 ADLs (i.e. ambulation, continence, transfers, dressing, feeding, bathing); and
- 3. Member/Enrollee is in renal failure, not receiving dialysis and one of the following:
 - a. Serum Creatinine > 8 mg/dl (> 6 diabetes), or
 - b. Creatinine clearance < 15 ml/min.

I. *Stroke* – meets ALL of the following:

- 1. PPS or KPS < 40%; and
- 2. Inadequate oral intake with one of the following:
 - a. Weight loss of > 10% body weight in up to 6 months, or > 7.5% in up to three months, or
 - b. Serum albumin < 2.5, or
 - c. Recurrent aspiration, or
 - d. Dysphagia and declining tube feeding and hydration.

J. *Coma* – member/enrollee is comatose with at least three of the following on day 3 of coma:

- 1. Abnormal brain stem response,
- 2. Absent verbal response,
- 3. Absent withdrawal to painful stimuli,
- 4. Creatinine > 1.5.



- **K.** Non-Disease Specific Decline in Clinical Status (the presence of significant comorbidities should be considered when using these criteria), ALL of the following:
 - 1. Irreversible decline, based on both baseline and follow-up determinations; and
 - 2. Clinical deterioration based on:
 - a. Progressive dependence for ADLs, or
 - b. Decreasing KPS or PPS from < 70%, or
 - c. Increasing frequency of ER visits or hospitalizations, or
 - d. Worsening of:
 - i. clinical status such as recurrent infections, inanition with progressive weight loss, dysphagia, or decreasing albumin, or
 - ii. signs such as hypotension, ascites, edema, pleural or pericardial disease, or decreased consciousness, or
 - iii. symptoms such as intractable dyspnea, cough, nausea, diarrhea, or pain, or
 - iv. laboratory results arterial blood gases, tumor markers, electrolytes, creatinine, or liver function tests; or
 - e. Progressive or stage 3-4 decubiti.

III.Intensity Of Service

Authorization is required prior to the initiation of hospice services, *for each benefit period*, and for *each change* in the level of intensity of service. Changes in level of care must be reviewed to determine medical necessity. The level of care and the dates of service requested must be specified. Only one level of care may be authorized for each day of hospice care provided to an eligible member/enrollee. *The appropriate HCPCS or revenue (rev) code must be billed according to applicable contract provisions*.

- **A.** Routine Hospice Home Care (HCPCS T2042 or rev code 0651)
 - 1. Routine hospice home care is medically necessary when < 8 hours of nursing care, which may be intermittent, is required in a 24-hour period. 90 days of routine hospice care may be approved
- **B.** Continuous Hospice Home Care (HCPCS T2043 or rev code 0652)
 - 1. Continuous hospice home care is medically necessary to maintain the member/enrollee at home, when the member/enrollee requires ≥ 8 hours of nursing care in a 24 hour period (begins and ends at midnight). Up to 5 days of continuous home hospice care may be approved with ongoing concurrent review for additional days required
- C. Inpatient Respite Hospice Care (HCPCS T2044 or rev code 0655)
 - 1. Respite hospice care is medical necessary to relieve family member's/enrollee's or other primary caregivers of care duties for no more than 5 consecutive days for any given episode of respite. Respite care is short term facility-based care, and not residential or custodial care. Up to 5 days per episode of inpatient respite care may be approved
- **D.** General Inpatient, Short Term (non-respite) Hospice Care (HCPCS T2045 or rev code 0656)



- 1. General inpatient, short term (non-respite) care services are medically necessary when the intensity or scope of care needed during an acute crisis is not feasible in the home setting and requires frequent adjustment by the member's/enrollee's care team; and
- 2. The individual treatment plan is specifically directed at acute symptom management and/or pain control.

Up to 5 days of general inpatient, short team may be approved with ongoing concurrent review for additional days required.

IV. Hospice services are considered **NOT medically necessary** under the following circumstances:

- **A.** Member/Enrollee with any of the following as the sole diagnosis:
- 1. Debility or unspecified debility, or
- 2. Failure to thrive; or
- **B.** The member/enrollee is no longer considered terminally ill as evidenced by a review of the medical documentation; or
- C. Services, supplies or procedures that are directed towards curing the terminal condition, with the possible exception of children covered under Medicaid or CHIP, or
- **D.** Member/Enrollee chooses to revoke the hospice election by submitting a signed, written statement with the effective date of the revocation; or
- **E.** Member/Enrollee is discharged from hospice services; i.e. member/enrollee is no longer considered terminally ill, member/enrollee refuses services or is uncooperative, moves out of the area, or transfers to a non-covered hospice program. In the event a member/enrollee is discharged from hospice, benefit coverage would be available as long as the member/enrollee remained eligible for coverage of medical services.

Subsequent Requests

Authorization is required for each change in the level of intensity of service. Only one level of care may be authorized for each day of hospice care provided to an eligible member/enrollee. The appropriate HCPCS or revenue (rev) code must be billed according to applicable contract provisions.

It is the policy of PHW that subsequent requests for hospice are medically necessary when meeting one of the following:

I. Request for continuation of routine home care for subsequent recertification period. Continuation of home care for subsequent recertification periods is medically necessary for additional 90 day periods following submission of a renewed hospice medical director certification of terminal illness.

II. Change to a higher intensity of service from routine hospice, one of the following:

A. Continuous Hospice Home Care (HCPCS T2043 or rev code 0652)

Continuous hospice home care is medically necessary to maintain the member/enrollee at home, when the member requires ≥ 8 hours of nursing care in a 24 hour period (begins and ends at midnight). Up to 5 days of continuous home hospice care may be approved with ongoing concurrent review for additional days requested.



- **B.** *Inpatient Respite Hospice Care* (HCPCS T2044 or rev code 0655)
 - Respite hospice care is medically necessary to relieve family member's/enrollee's or other primary caregivers of care duties for no more than 5 consecutive days per episode. Respite care is short term inpatient care, and not residential or custodial care. Up to 5 days per episode of inpatient respite care may be approved.
- **C.** General Inpatient, Short Term (non-respite) Hospice Care (HCPCS T2045 or rev code 0656), meets both:
 - 1. The intensity or scope of care needed during an acute crisis is not feasible in the home setting and requires frequent adjustment by the member's/enrollee's care team; and
 - 2. The treatment plan is specifically directed at acute symptom management and/or pain control.

Up to 5 days of general inpatient, short term care may be approved with ongoing concurrent review for additional days requested.

III. Change to routine home care following higher intensity of service

Continuation of routine home care following a higher level of care is medically necessary for the duration of the current 90-day certification period.

Definitions

Levels of Care - four distinct levels of care are available

A. Routine Hospice Home Care

Routine hospice home care is care provided in the member's/enrollee's home and is related to the terminal diagnosis and plan of care written for the member/enrollee. Routine hospice home care may include up to 8 hours of skilled nursing care in a 24-hour period. This care may be provided in a private residence, hospice residential care facility, nursing facility, or an adult care home.

B. Continuous Hospice Home Care

Continuous hospice home care consists primarily of skilled nursing care at home during brief periods of crisis in order to achieve palliation or management of acute medical symptoms and only as necessary to maintain the member/enrollee at home. Continuous care must provide a minimum of 8 hours of nursing care in a 24 hour period, which begins and ends at midnight; the nursing care need not be continuous.

Continuous care may be supplemented by home health aide or homemaker services, but at least 50% of the total care must be provided by a nurse, and the care required must be predominantly nursing, rather than personal care or assistance with activities of daily living. Continuous hospice home care is not intended to be respite care or an alternative to paid caregivers or placement in another setting. Continuous hospice home care may include any of the services outlined in the covered services definition below.

C. Respite Hospice Care



Short-term inpatient respite hospice care is provided in an approved inpatient hospice facility, hospital or nursing home for no more than 5 consecutive days for any given episode of respite. It is allowed to relieve family member's/enrollee's or other primary caregivers of the primary caregiving duties. A primary caregiver is an individual, designated by the member/enrollee, who is responsible for the 24-hour care and support of the member/enrollee in his or her home. A primary caregiver is not required to elect hospice if it has been determined by the hospice team that the member/enrollee is safe at home alone at the time of the election.

D. General Inpatient, Short Term (non-respite) Hospice Care

General inpatient care, under the hospice benefit, is short-term, non-respite hospice care and is appropriate when provided in an approved hospice facility, hospital or nursing home. It is specifically used for pain control and symptom relief which is related to the terminal diagnosis and cannot be managed in the home hospice setting. The goal is to stabilize the member/enrollee and return him/her to the home environment. General inpatient, short term hospice care may include any of the services outlined in the covered

Certification Periods

services definition below.

Certification (benefit) periods include an initial 90-day benefit period, followed by a second-90 day benefit period, followed by an unlimited number of 60-day benefit periods. Hospice care is continuous from one period to another, unless the member/enrollee revokes, or the hospice provider discharges or does not recertify.

Discontinuation of Hospice

If a member/enrollee revokes or is discharged from hospice care, the remaining days in the benefit period are lost. If/when the member/enrollee meets the hospice coverage requirements, they can re-elect the hospice benefit, and will begin with the next benefit period.

Covered Services

When the above coverage criteria are met, the following hospice care services may be covered as part of the hospice treatment plan:

- **A.** Physician services
- **B.** Appropriate skilled nursing services
- **C.** Home health aide services (including intermittent assistance with bathing, shaving, grooming, and other personal needs)
- **D.** Physical and/or occupational therapy
- E. Speech therapy services for dysphagia/feeding therapy
- F. Medical social services
- **G.** Counseling services (e.g., dietary, bereavement)
- H. Short-term inpatient care
- I. Prescription drugs (all drugs and biologicals that are necessary for the palliation and management of the terminal illness and related conditions)
- J. Consumable medical supplies (e.g., bandages, catheters) used by the hospice team.
- **K.** Durable medical equipment (e.g., hospital beds, bedside commodes)



Non-covered Services

The following services are considered not covered as part of the hospice treatment plan:

- **A.** Services during an acute inpatient stay for a diagnosis that is unrelated to the terminal illness for which the member/enrollee is receiving hospice care
- B. Services for individuals no longer considered terminally ill
- C. Services, supplies or procedures, or medication that are directed towards curing the terminal condition
- **D.** Ongoing or continuous services to primarily aid in the performance of activities of daily living
- **E.** Nutritional supplements, vitamins, minerals and non-prescription drugs
- F. Medical supplies unrelated to the palliative care to be provided
- **G.** Services for which any other benefits apply.

Provider Responsibilities

The hospice provider is responsible for:

- A. Verifying member/enrollee eligibility
- **B.** Obtaining authorization to provide hospice services before hospice care is initiated
- C. Notifying the health plan of any significant change in the member's/enrollee's status or condition including revisions to treatment plans and goals
- **D.** Requesting each change in the level of hospice service including discharge from hospice.

Background

Hospice is a coordinated, integrated program developed by a multidisciplinary team of professionals to provide end-of-life care, which is primarily focused on relieving pain *and* symptoms specifically related to the terminally ill diagnosis of member'/enrollee's with a life expectancy of six months or less. Most hospice services are provided at home, by a licensed certified hospice provider, under the direction of an attending physician, who may be the member's/enrollee's primary care physician or the hospice medical director. Hospice services are provided under a plan of care designed by the multidisciplinary team to meet the needs of member/enrollees who are terminally ill, as well as their families.

Hospice services include skilled nursing, homemaker and home health aide services, physician services, physical, occupational and speech therapy, medical social services, volunteer services, nutritional, spiritual, psychosocial/supportive and bereavement counseling related to the management of the terminal illness. Hospice includes drugs and biologics related to the management of the terminal illness, to relieve pain, provide hydration and to deliver enterals as a primary source of nutrition. Durable medical equipment and medical supplies are also included in hospice, when related to the management of a terminal illness.

Appendices

Appendix A: Palliative Performance Scale (PPS)

¹ National Hospice and Palliative Care Organization, Facts and Figures: Hospice Care in America, 2011 Edition



PPS Level	Ambulation	Activity & Evidence of Disease	Self-care	Intake	Conscious Level
100%	Full	Normal activity & work	Full	Normal	Full
000/	- 11	No evidence of disease	7 11	27 1	7.11
90%	Full	Normal activity & work Some evidence of disease	Full	Normal	Full
80%	Full	Normal activity with effort Some evidence of disease	Full	Normal or reduced	Full
70%	Reduced	Unable normal job/work Significant disease	Full	Normal or reduced	Full
60%	Reduced	Unable hobby/housework Significant disease	Occasional assistance needed	Normal or reduced	Full or confusion
50%	Mainly sit/lie	Unable to do any work Extensive disease	Considerable assistance required	Normal or reduced	Full or confusion
40%	Mainly in bed	Unable to do most activity Extensive disease	Mainly assistance	Normal or reduced	Full or drowsy +/-confusion
30%	Totally bed bound	Unable to do any activity Extensive disease	Total care	Normal or reduced	Full or drowsy +/-confusion
20%	Totally bed bound	Unable to do any activity Extensive disease	Total care	Minimal to sips	Full or drowsy +/-confusion
10%	Totally bed bound	Unable to do any activity Extensive disease	Total care	Mouth care only	Full or drowsy +/-confusion
0%	Death				

Appendix B: Karnofsky Performance Status Scale (KPS) Definitions Rating (%) Criteria

Activity Level	Score	Detailed Activity Level
Able to carry on normal	100	Normal no complaints; no evidence of disease.
activity and to work; no	90	Able to carry on normal activity; minor signs or
special care needed.		symptoms of disease.
	80	Normal activity with effort; some signs or symptoms of
		disease.
Unable to work; able to	70	Cares for self; unable to carry on normal activity or to
live at home and care for		do active work.
most personal needs;	60	Requires occasional assistance, but is able to care for
varying amount of		most of his personal needs.
assistance needed.	50	Requires considerable assistance and frequent medical
		care.
	40	Disabled; requires special care and assistance.



Activity Level	Score	Detailed Activity Level
Unable to care for self;	30	Severely disabled; hospital admission is indicated
requires equivalent of		although death not imminent.
institutional or hospital	20	Very sick; hospital admission necessary; active
care; disease may be		supportive treatment necessary.
progressing rapidly.	10	Moribund; fatal processes progressing rapidly.

Appendix C: Functional Assessment Staging Test (FAST) for Alzheimer's disease

Stage	Stage Name	Characteristic
1	Normal aging	No deficits
2	Possible mild cognitive impairment	Subjective functional deficit
3	Mild cognitive impairment	Objective functional deficit interferes with a
		person's most complex tasks
4	Mild dementia	IADLs become affected, such as bill paying,
		cooking, cleaning, traveling
5	Moderate dementia	Needs help selecting proper attire
6a	Moderately severe dementia	Needs help putting on clothes
6b	Moderately severe dementia	Needs help bathing
6c	Moderately severe dementia	Needs help toileting
6d	Moderately severe dementia	Urinary incontinence
6e	Moderately severe dementia	Fecal incontinence
7a	Severe dementia	Speaks 5-6 words during day
7b	Severe dementia	Speaks only 1 word clearly
7c	Severe dementia	Can no longer walk
7d	Severe dementia	Can no longer sit up
7e	Severe dementia	Can no longer smile
7f	Severe dementia	Can no longer hold up head

Coding Implications

The following codes are for informational purposes only. They are current at time of review of this policy. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS	Description
Codes	
T2042	Hospice routine home care; per diem
T2043	Hospice continuous home care; per hour
T2044	Hospice inpatient respite care, per diem
T2045	Hospice general inpatient care; per diem
T2046	Hospice long-term care, room and board only; per diem
G0337	Hospice evaluation and counseling services, preelection
Revenue	
Code	
0651	Hospice routine home care; per diem



0652	Hospice continuous home care, per hour
0655	Hospice inpatient respite care, per diem
0656	Hospice general inpatient, non-respite care, per diem
0658	Hospice room and board, nursing facility
0657	Hospice charges for services furnished to patients by physician or nurse practitioner employees, or physicians or nurse practitioners receiving compensation from the hospice. Physician services performed by a nurse practitioner require the addition of the modifier GV in conjunction with revenue code 0657.

Reviews, Revisions, and Approvals	Revision Date	A p r o v a l D a t
Removed requirement of documentation that member/enrollee must no longer be seeking curative treatment, with the possible exception of CHIP. Intensity of Service (Initial): removed redundant language regarding requirement for authorization of each request. Added section for subsequent requests. Section I.E Dementia: Removed "Inability to ambulate" from criteria as this is	05/18	
included in the FAST stage 7 criteria; added septicemia to list of medical complications (E.2.C). References reviewed and updated. Specialist reviewed.		
Annual review complete. Replaced "glomerular filtration rate" with creatinine clearance in H.3.b and H.3.c. Updated "creatinine clearance < 10 (or < 15 with diabetes), or creatinine clearance < 15 with CHF (or < 20 with diabetes and CHF)" to "creatinine clearance <15 ml/min" per LCD L34538 update. Moved hospice description from background section to policy description section. Replaced all instances of "member" with "member/enrollee". Codes reviewed. Revised forced vital capacity (FVC) in II.B.3.a. from < 40% to < 30%. Revised II.F.b.3 from, "> 33% lean body mass," to, "loss of at least 10% lean body mass." Changed "review date" in the header to "date of last revision" and "date" in the revision log header to "revision date." References reviewed, updated and reformatted. Reviewed by specialist.	07/26/2022	

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