CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-02 Medicare Benefit Policy	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 117	**Date: DECEMBER 18, 2009**
	Change Request 6557

SUBJECT: Coverage of Kidney Disease Patient Education Services

I. SUMMARY OF CHANGES: MIPPA Section 152(b) adds Kidney Disease Patient Education services as a Medicare covered benefit for Medicare beneficiaries diagnosed with Stage IV chronic kidney disease (CKD). The services are designed to provide beneficiaries with comprehensive information regarding the management of comorbidities, including for purposes of delaying the need for dialysis; prevention of uremic complications; and each option for renal replacement therapy. The benefit is also designed to be tailored to individual needs and provide the beneficiary with the opportunity to actively participate in his/her choice of therapy.

New / Revised Material
Effective Date: January 1, 2010
Implementation Date: April 5, 2010

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	15/Table of Contents
N	15/310/Kidney Disease Patient Education Services
N	15/310/310.1/Beneficiaries Eligible for Coverage
N	15/310/310.2/Qualified Person
N	15/310/310.3/Limitations for Coverage
N	15/310/310.4/Standards for Content
N	15/310/310.5/Outcomes Assessment

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

Unless otherwise specified, the effective date is the date of service.

Attachment – Business Requirements

Pub. 100-02	Transmittal: 117	Date: December 18,2009	Change Request: 6557

SUBJECT: Coverage of Kidney Disease Patient Education Services

Effective Date: January 1, 2010
Implementation Date: April 5, 2010

I. GENERAL INFORMATION

A. Background: By definition, chronic kidney disease (CKD) is kidney damage for 3 months or longer, regardless of the cause of kidney damage. CKD typically evolves over a long period of time and patients may not have symptoms until significant, possibly irreversible, damage has been done. Complications can develop from kidneys that do not function properly, such as high blood pressure, anemia, and weak bones. When chronic kidney disease progresses, it may lead to kidney failure, which requires artificial means to perform kidney functions (dialysis) or a kidney transplant to maintain life.

Patients can be classified into 5 stages of CKD, based on how quickly blood is filtered through the kidneys (glomerular filtration rate, or GFR), with stage I having kidney damage with normal or increased GFR to stage V with kidney failure, also called end-stage renal disease (ESRD). Once patients with CKD are identified, treatment is available to help prevent complications of decreased kidney function, slow the progression of kidney disease, and reduce the risk of other diseases such as heart disease.

Individuals with CKD may benefit from kidney disease education (KDE) interventions due to the large amount of medical information that could affect patient outcomes, including the increasing emphasis on self-care and patients' desire for informed, autonomous decision-making. Pre-dialysis education can help patients achieve better understanding of their illness, dialysis modality options, and may help delay the need for dialysis. Education interventions should be patient-centered, encourage collaboration, offer support to the patient, and be delivered consistently.

B. Policy: Section 152(b) of the Medicare Improvements for Patients and Providers Act (MIPPA) added KDE services as a Medicare Part B covered benefit for Medicare beneficiaries diagnosed with Stage IV CKD (severe decrease in GFR; GFR value of 15-29 ml/min/1.73 m^2), who have received a referral from the physician managing the beneficiary's kidney condition. The Centers for Medicare & Medicaid Services (CMS) published regulations implementing this provision at 42 CFR 410.48. KDE services will be tailored to meet the needs of the individual beneficiary involved, designed to provide beneficiaries opportunities to actively participate in the choice of therapy, and provide comprehensive information regarding:

- Management of comorbidities, including for the purpose of delaying the need for dialysis;
- Prevention of uremic complications; and
- Each option for renal replacement therapy (including hemodialysis and peritoneal dialysis, at home and in-facility, dialysis access options, and transplantation);

Contractors will pay for KDE services that meet the following conditions:

- No more than 6 sessions of KDE services are provided in a beneficiary's lifetime,

- Sessions billed in increments of 1 hour (In order to bill for a session, a session must be at least 31 minutes in duration. A session that lasts at least 31 minutes, but less than 1 hour still constitutes 1 session.),
- Sessions furnished either individually or in a group setting of 2 to 20 individuals, that need not all be Medicare beneficiaries, and
- Furnished, upon the referral of the physician managing the beneficiary's kidney condition, by a qualified person meaning a:

    - physician, physician's assistant, nurse practitioner, or clinical nurse specialist;
    - hospital, critical access hospital (CAH), comprehensive outpatient rehabilitation facility (CORF), home health agency (HHA), or hospice, that is located in a rural area; or
    - hospital or CAH that is paid as if it were located in a rural area (hospitals and CAHs reclassified as rural under section 42 CFR 412.103).

NOTES:

- In section 42 CFR 485.610(b), a CAH (TOB 85X) is a rural provider. Therefore, a CAH is designated as a qualified person for purposes of furnishing KDE services irrespective of the provider's geographic location.

- Renal dialysis facilities (TOB 72X) are precluded from providing KDE services irrespective of the provider's geographic location.

CMS will issue 2 new HCPCS codes to be used to report covered KDE services in the January 2010 IOCE and the Medicare Physician Fee Schedule Database (MPFSDB). CMS will identify the payment amounts in the final 2010 Medicare Physician Fee Schedule (MPFS).

G0420: Face-to-face educational services related to the care of chronic kidney disease; individual, per session, per one hour

G0421: Face-to-face educational services related to the care of chronic kidney disease; group, per session, per one hour

II. BUSINESS REQUIREMENTS TABLE

Use"Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6557.1	Effective for claims with dates of service on and after January 1, 2010, contractors shall pay claims for KDE services when provided to patients with stage IV CKD subject to criteria in Pub 100-02, Medicare Benefit Policy Manual, chapter 15, section 310 and Pub 100-04, Medicare Claims Processing Manual, chapter 32, section 20.	X		X	X	X	X				

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6557.2	Contractors shall pay claims for KDE services containing HCPCS codes G0420 or G0421 with ICD-9 diagnosis code 585.4 (chronic kidney disease, Stage IV (severe)).	X		X	X	X	X				Jan. 2010 MPFSDB, Jan 2010 IOCE
6557.2.1	Contractors shall pay claims for KDE services containing HCPCS codes G0420 or G0421 on TOBs 12X, 13X, 22X, 23X, 34X, 75X, 81X, 82X and 85X under the MPFS.	X		X		X	X				
6557.2.2	Contractors shall deny claims for KDE services billed without diagnosis code 585.4 and use the following messages: MSN 16.10 Medicare does not pay for this item or service. Spanish Version: "Medicare no paga por este artículo o servicio." CARC 167 – This (these) diagnosis(es) is (are) not covered.	X		X	X	X	X				
6557.3	Effective for claims with dates of service on or after January 1, 2010, CWF shall create a line item edit to ensure that claims with HCPCS G0420 or G0421 with ICD-9 585.4 billed for KDE services are not allowed on both a professional and institutional claim on the same service date. **NOTE:** CWF shall allow contractors to override the edit if the denial is overturned on appeal.	X			X		X			X	
6557.3.1	Contractors shall deny subsequent claims for KDE services if two claims are billed (professional and institutional) on the same service date. Use the following messages: MSN 15.5 – The information provided does not support the need for similar services by more than one doctor during the same time period. Spanish Version: "La información proporcionada no confirma la necesidad por servicios similares por más de un médico durante el mismo periodo."	X		X	X	X					

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	CARC – 18 – Duplicate claim/service.										
6557.4	Effective for claims with dates of service on or after January 1, 2010, CWF shall create an edit to allow no more than 6 sessions of KDE services, HCPCS G0420 or G0421 with ICD-9 585.4, in a beneficiary's lifetime.	X			X		X			X	
6557.4.1	Contractors shall deny claims containing HCPCS G0420 or G0421 with ICD-9 585.4, for KDE services when submitted for more than 6 sessions, using the following messages: MSN 15.22 - The information provided does not support the need for this many services or items in this period of time so Medicare will not pay for this item or service. Spanish Version: "La información proporcionada no justifica la necesidad de esta cantidad de servicios o artículos en este periodo de tiempo por lo cual Medicare no pagará por este artículo o servicio." CARC 119 - Benefit maximum for this time period or occurrence has been reached.	X		X	X	X					
6557.5	Contractors shall pay for KDE services submitted on one of the following Type Of Bills (TOBs): 12X, 13X, 22X, 23X, 34X, 75X, 81X and 82X only when received from a provider located in a rural area.	X		X		X	X				
6557.5.1	Contractors shall pay for KDE services when TOB 85X is received irrespective of the provider's geographic classification.	X		X			X				
6557.5.2	Contractors shall pay for KDE services when the above TOBs are received from a section 401 hospital (i.e., the provider is found on the annually updated Table 9C of the IPPS Rule. See attachment A.).	X		X		X	X				
6557.6	Contractors shall only allow HCPCS codes G0420 and G0421 with ICD-9 code 585.4, to be billed with revenue code 0942 on the following TOBs: 22X, 23X, 34X, 75X, 81X, 82X and 85X.	X		X		X	X				
6557.6.1	Contractors shall update the revenue code file	X				X					

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	to allow hospice claims to bill for revenue code 0942.										
6557.6.1.1	Contractors shall return to the provider any hospice claims billing for revenue code 0942 when other services are also included on the claim.	X				X	X				
6557.6.1.2	CWF shall ensure that the hospice benefit period is not updated from hospice claims billing for KDE services.									X	
6557.6.1.3	Contractors shall ensure that hospice claims billed for 0942 are paid from the Part B Trust Fund.						X				
6557.6.1.4	Contractors shall ensure that hospice claims, TOBs 81X and 82X, contain value code 61 or G8 when billing for KDE services, HCPCS codes G0420 and G0421.	X		X			X				
6557.7	Contractors shall deny payment for KDE services when rendered in an urban area unless the provider is a 401 hospital (see 6557.5.2), or submits on TOB 85X.	X		X		X	X				
6557.7.1	Contractors shall use the following messages when denying KDE services: MSN 21.6 - This item or service is not covered when performed, referred or ordered by this provider. Spanish Version: "Este servicio no está cubierto cuando es rendido, referido u ordenado por este proveedor." CARC 170 - Payment is denied when performed/billed by this type of provider.	X		X		X					
6557.8	Contractors shall pay for KDE services for hospitals in Maryland under the jurisdiction of the Health Services Cost Review Commission (HSCRC), TOBs 12X or 13X, on an inpatient Part B or outpatient basis in accordance with the terms of the Maryland Waiver.	X		X	X		X				
6557.9	Contractors shall not search their files for claims with dates of service between January 1, 2010, and the implementation of this CR. However, contractors may adjust claims brought to their attention.	X		X	X	X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6557.10	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X	X	X					

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
6557.5	Rural providers can be identified through a rural CBSA on the Provider Specific File (i.e., _ _ _16) or through a rural designation on the Medicare ZIP Code File.
6557.5.2	Table 9C can be found in the "Wage Index Files" of the Acute Inpatient PPS. See Attachment A.
6557.2.2 6557.3.1 6557.4.1 6557.7.1	If an advanced beneficiary notice (ABN) is provided with a GA modifier indicating there is a signed ABN on file, contractors shall use Group Code PR (Patient Responsibility) and the liability falls to the beneficiary. If an ABN is provided with a GZ modifier indicating no ABN was provided, contractors shall use Group Code CO (Contractual Obligation) and the liability falls to the provider.

Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s):
Jamie Hermansen, 410-786-2064, jamie.hermansen@cms.hhs.gov (coverage).
Patricia Brocato-Simons, 410-786-0261, patricia.brocatosimons@cms.hhs.gov (coverage).
April Billingsley, 410-786-0140, april.billingsley@cms.hhs.gov (practitioner claims processing).
William Ruiz, 410-786-9283, william.ruiz@cms.hhs.gov (institutional claims processing).

Post-Implementation Contact(s): CMS Regional Offices

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs),* and/or *Carriers*:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: *For Medicare Administrative Contractors (MACs)*:

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Attachment

Attachment A

TABLE 9C.--HOSPITALS REDESIGNATED AS RURAL UNDER SECTION 1886(d)(8)(E) OF THE ACT - FY 2010		
Provider No.	**Geographic CBSA**	**Redesignated Rural Area**
040118	27860	04
050192	23420	05
050528	32900	05
050618	40140	05
070004	07	07
100048	37860	10
100118	37380	10
100134	27260	10
140167	14	14
170137	29940	17
180038	36980	18
220051	38340	22
230078	35660	23
250017	25	25
260006	41140	26
260034	28140	26
260047	27620	26
260195	44180	26
300023	40484	33
330235	33	33
330268	10580	33
340010	24140	34
360125	36	36
370054	36420	37
380040	13460	38
390130	27780	39
390183	39	39
390233	49620	39
450052	45	45
450078	10180	45
450243	10180	45
450348	45	45
490116	13980	49
500148	48300	50

Medicare Benefit Policy Manual
Chapter 15 – Covered Medical and Other Health Services

Table of Contents
(Rev. 117, 12-18-09)

310 – Kidney Disease Patient Education Services

(Rev. 117; Issued: 12-18-09; Effective Date: 01-01-10; Implementation Date: 04-05-10)

By definition, chronic kidney disease (CKD) is kidney damage for 3 months or longer, regardless of the cause of kidney damage. CKD typically evolves over a long period of time and patients may not have symptoms until significant, possibly irreversible, damage has been done. Complications can develop from kidneys that do not function properly, such as high blood pressure, anemia, and weak bones. When CKD progresses, it may lead to kidney failure, which requires artificial means to perform kidney functions (dialysis) or a kidney transplant to maintain life.

Patients can be classified into 5 stages based on their glomerular filtration rate (GFR, how quickly blood is filtered through the kidneys), with stage I having kidney damage with normal or increased GFR to stage V with kidney failure, also called end-stage renal disease (ESRD). Once patients with CKD are identified, treatment is available to help prevent complications of decreased kidney function, slow the progression of kidney disease, and reduce the risk of other diseases such as heart disease.

Beneficiaries with CKD may benefit from kidney disease education (KDE) interventions due to the large amount of medical information that could affect patient outcomes, including the increasing emphasis on self-care and patients' desire for informed, autonomous decision-making. Pre-dialysis education can help patients achieve better understanding of their illness, dialysis modality options, and may help delay the need for dialysis. Education interventions should be patient-centered, encourage collaboration, offer support to the patient, and be delivered consistently.

Effective for claims with dates of service on and after January 1, 2010, Section 152(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) covers KDE services under Medicare Part B. KDE services are designed to provide beneficiaries with Stage IV CKD comprehensive information regarding: the management of comorbidities, including delaying the need for dialysis; prevention of uremic complications; all therapeutic options (each option for renal replacement therapy, dialysis access options, and transplantation); ensuring that the beneficiary has opportunities to actively participate in his/her choice of therapy; and that the services be tailored to meet the beneficiary's needs.

Regulations for KDE services were established at 42 CFR 410.48. Claims processing instructions and billing requirements can be found in Pub. 100-04, Medicare Claims Processing Manual, Chapter 32 – Billing Requirements for Special Services, Section 20.

310.1 - Beneficiaries Eligible for Coverage

(Rev. 117; Issued: 12-18-09; Effective Date: 01-01-10; Implementation Date: 04-05-10)

Medicare Part B covers outpatient, face-to-face KDE services for a beneficiary that:

- *is diagnosed with Stage IV CKD, using the Modification of Diet in Renal Disease (MDRD) Study formula (severe decrease in GFR, GFR value of 15-29 mL/min/1.73 m^2), and*

- *obtains a referral from the physician managing the beneficiary's kidney condition. The referral should be documented in the beneficiary's medical records.*

310.2 - Qualified Person

(Rev. 117; Issued: 12-18-09; Effective Date: 01-01-10; Implementation Date: 04-05-10)

Medicare Part B covers KDE services provided by a 'qualified person,' meaning a:

- *physician (as defined in section 30 of this chapter),*

- *physician assistant, nurse practitioner, or clinical nurse specialist (as defined in sections 190, 200, and 210 of this chapter),*

- *hospital, critical access hospital (CAH), skilled nursing facility (SNF), comprehensive outpatient rehabilitation facility (CORF), home health agency (HHA), or hospice, if the KDE services are provided in a rural area (using the actual geographic location core based statistical area (CBSA) to identify facilities located in rural areas), or*

- *hospital or CAH that is treated as being rural (was reclassified from urban to rural status per 42 CFR 412.103).*

NOTE: *The "incident to" requirements at section 1861(s)(2)(A) of the Social Security Act (the Act) do not apply to KDE services.*

The following providers are not 'qualified persons' and are excluded from furnishing KDE services:

- *A hospital, CAH, SNF, CORF, HHA, or hospice located outside of a rural area (using the actual geographic location CBSA to identify facilities located outside of a rural area), unless the services are furnished by a hospital or CAH that is treated as being in a rural area; and*

- *Renal dialysis facilities.*

310.3 - Limitations for Coverage

(Rev. 117; Issued: 12-18-09; Effective Date: 01-01-10; Implementation Date: 04-05-10)

Medicare Part B covers KDE services:

- *Up to six (6) sessions as a beneficiary lifetime maximum. A session is 1 hour. In order to bill for a session, a session must be at least 31 minutes in duration. A session that lasts at least 31 minutes, but less than 1 hour still constitutes 1 session.*

- *On an individual basis or in group settings; if the services are provided in a group setting, a group consists of 2 to 20 individuals who need not all be Medicare beneficiaries.*

NOTE: *Two HCPCS codes were created for this benefit and one or the other must be present, along with ICD-9-CM code 585.4 (chronic kidney disease, Stage IV (severe)), in order for a claim to be processed and paid correctly. They are:*

- *G0420: Face-to-face educational services related to the care of chronic kidney disease; individual, per session, per one hour*

- *G0421: Face-to-face educational services related to the care of chronic kidney disease; group, per session, per one hour*

310.4 – Standards for Content

(Rev. 117; Issued: 12-18-09; Effective Date: 01-01-10; Implementation Date: 04-05-10)

Medicare Part B covers KDE services, provided by a qualified person, which provide comprehensive information regarding:

A. The management of comorbidities, including delaying the need for dialysis, which includes, but is not limited to, the following topics:

- *Prevention and treatment of cardiovascular disease,*
- *Prevention and treatment of diabetes,*
- *Hypertension management,*
- *Anemia management,*
- *Bone disease and disorders of calcium and phosphorus metabolism management,*
- *Symptomatic neuropathy management, and*
- *Impairments in functioning and well-being.*

B. Prevention of uremic complications, which includes, but is not limited to, the following topics:

- *Information on how the kidneys work and what happens when the kidneys fail,*
- *Understanding if remaining kidney function can be protected, preventing disease progression, and realistic chances of survival,*
- *Diet and fluid restrictions, and*

- *Medication review, including how each medication works, possible side effects and minimization of side effects, the importance of compliance, and informed decision making if the patient decides not to take a specific drug.*

C. *Therapeutic options, treatment modalities and settings, advantages and disadvantages of each treatment option, and how the treatments replace the kidney, including, but not limited to, the following topics:*

- *Hemodialysis, both at home and in-facility;*
- *Peritoneal dialysis (PD), including intermittent PD, continuous ambulatory PD, and continuous cycling PD, both at home and in-facility;*
- *All dialysis access options for hemodialysis and peritoneal dialysis; and*
- *Transplantation.*

D. *Opportunities for beneficiaries to actively participate in the choice of therapy and be tailored to meet the needs of the individual beneficiary involved, which includes, but is not limited to, the following topics:*

- *Physical symptoms,*
- *Impact on family and social life,*
- *Exercise,*
- *The right to refuse treatment,*
- *Impact on work and finances,*
- *The meaning of test results, and*
- *Psychological impact.*

310.5 - Outcomes Assessment

(Rev. 117; Issued: 12-18-09; Effective Date: 01-01-10; Implementation Date: 04-05-10)

Qualified persons that provide KDE services must develop outcomes assessments that are designed to measure beneficiary knowledge about CKD and its treatment. The assessment must be administered to the beneficiary during a KDE session, and be made available to the Centers for Medicare & Medicaid Services (CMS) upon request. The outcomes assessments serve to assist KDE educators and CMS in improving subsequent KDE programs, patient understanding, and assess program effectiveness of:

- *Preparing the beneficiary to make informed decisions about their healthcare options related to CKD, and*

- *Meeting the communication needs of underserved populations, including persons with disabilities, persons with limited English proficiency, and persons with health literacy needs.*