CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 4049	Date: May 11, 2018
	Change Request 10295

Transmittals 206 and 4016, dated April 3, 2018, are being rescinded and replaced by Transmittals 207 and 4049, dated, May 11, 2018to remove Pub. 100-04 business requirements 10295.04.1.1 and 10295.04.1.1.1 and to insert the appropriate policy language in both publications 100-3 and 100-04. All other information remains the same.

SUBJECT: Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform contractors that effective May 25, 2017, the Centers for Medicare and Medicaid Services (CMS) issued an NCD to cover SET for beneficiaries with IC for the treatment of symptomatic PAD.

EFFECTIVE DATE: May 25, 2017

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

IMPLEMENTATION DATE: July 2, 2018 - for MAC local edits and for Shared System edits

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-*Only One Per Row*.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	32/Table of Contents/390-Supervised Exercise Therapy (SET) for Treatment of Symptomatic Peripheral Artery Disease (PAD)
N	32/390.1/ General Billing Requirements
N	32/390.2/Coding Requirements for SET
N	32/390.3/Special Billing Requirements for Institutional Claims
N	32/390.4/Common Working File (CWF) Requirements
N	32/390.5/Applicable Medicare Summary Notice (MSN), Remittance Advice Remark Codes (RARC) and Claim Adjustment Reason Code (CARC) Messaging

III. FUNDING:

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

Attachment - Business Requirements

Transmittals 206 and 4016, dated April 3, 2018, are being rescinded and replaced by Transmittals 207 and 4049, dated, May 11, 2018to remove Pub. 100-04 business requirements 10295.04.1.1 and 10295.04.1.1.1 and to insert the appropriate policy language in both publications 100-3 and 100-04. All other information remains the same.

SUBJECT: Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD)

EFFECTIVE DATE: May 25, 2017

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

IMPLEMENTATION DATE: July 2, 2018 - for MAC local edits and for Shared System edits

I. GENERAL INFORMATION

- **A. Background:** Supervised exercise therapy (SET) involves the use of intermittent walking exercise which alternates periods of walking to moderate-to-maximum claudication, with rest. SET has been recommended as the initial treatment for patients suffering from intermittent claudication (IC), the most common symptom experienced by people with peripheral artery disease (PAD). Despite years of high-quality research illustrating the effectiveness of SET, more invasive treatment options (i.e., endovascular revascularization) have continued to increase. This has been partly attributed to patients having limited access to SET programs. There is currently no national coverage determination (NCD) in effect.
- **B.** Policy: On May 25, 2017, the Centers for Medicare and Medicaid Services (CMS) issued an NCD to cover SET for beneficiaries with IC for the treatment of symptomatic PAD. Up to 36 sessions over a 12 week period are covered if all of the following components of a SET program are met:

The SET program must:

- consist of sessions lasting 30-60 minutes comprising a therapeutic exercise-training program for PAD in patients with claudication;
- be conducted in a a hospital outpatient setting, or a physician's office;
- be delivered by qualified auxiliary personnel necessary to ensure benefits exceed harms, and who are trained in exercise therapy for PAD; and
- be under the direct supervision of a physician (as defined in 1861(r)(1), of the Social Security Act (the Act)), physician assistant, or nurse practitioner/clinical nurse specialist (as identified in 1861(aa)(5)) of (the Act)), who must be trained in both basic and advanced life support techniques. Beneficiaries must have a face-to-face visit with the physician responsible for PAD treatment to obtain the referral for SET. At this visit, the beneficiary must receive information regarding cardiovascular disease and PAD risk factor reduction, which could include education, counseling, behavioral interventions, and outcome assessments. Medicare Administrative Contractors (MACs) have the discretion to cover SET beyond 36 sessions over 12 weeks and may cover an additional 36 sessions (up to 72 sessions) over an extended period of time. Contractors shall accept the inclusion of the KX modifier on the claim line(s) as an attestation by the provider of the services that documentation is on file verifying that further treatment beyond the 36 sessions of SET over a 12 week period meets the requirements of the medical policy. SET is non-covered for beneficiaries with absolute contraindications to exercise as determined by their primary attending physician.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	R	espo							
			A/E		D			red-		Other
		1	MA	C	M E		_	tem tain		
		A	В	Н	-	F	M	ı		
				Н	M	Ι	C	M		
				Н	A C	S S	S	S	F	
10295 - 04.1	Effective for claims with date of services on or after May 25, 2017, contractors shall accept claims for SET for beneficiaries with IC for the treatment of symptomatic PAD, with a referral from the physician responsible for PAD treatment using CPT Code 93668. NOTE: CPT Code 93668 will appear on the Medicare Physician Fee Schedule Data Base	X	X			X				IOCE
	effective January 1, 2018.									
10295 - 04.1.1	This business requirement has been removed.		X							
10295 - 04.1.1.1	This business requirement has been removed.		X							
10295 - 04.1.2	Contractors shall pay claims for SET services containing CPT code 93668 on Types of Bill (TOBs) 13X under OPPS and 85X based on reasonable cost.	X				X				
10295 - 04.1.2.1	Contractors shall pay claims for SET services containing CPT 93668 with revenue codes 096X, 097X, or 098X when billed on TOB 85X Method II based on 115% of the lesser of the fee schedule amount or the submitted charge.	X				X				
10295 - 04.1.2.2	Contractors shall deny line items on claims for SET services (CPT code 93668) when provided on other than TOBs 13X and 85X using:	X				X				
	MSN 15.20: "The following policies NCD 20.35 were used when we made this decision."									
	Spanish Version – "Las siguientes políticas NCD 20.35 fueron utilizadas cuando se tomó									

Number	Requirement	Re	espo	nsil						
			A/B	}	D		Sha			Other
		N	MA(\mathbb{C}	M		Sys			
					Е		aint			
		A	В	H H	M	F I	M C			
				Н	A	S	S	S	F	
					C	S				
	esta decisión."									
	CARC 58: "Treatment was deemed by the									
	payer to have been rendered in an									
	inappropriate or invalid place of service.									
	NOTE: Refer to the 832 Healthcare Policy									
	Identification Segment (loop 2110 Service payment Information REF), if present.									
	payment information REF), if present.									
	RARC N386: "This decision was based on a									
	National Coverage Determination 20.35 (NCD). An NCD provides a coverage									
	determination as to whether a particular item									
	or service is covered. A copy of this policy is									
	available at www.cms.gov/mcd/search.asp. If									
	you do not have web access, you may contact									
	the contractor to request a copy of the NCD.									
10005 011001	(2 : : : : : : : : : : : : : : : : : : :	•				**				
10295 - 04.1.2.2.1	(Continuation of BR 10295-04.1.2.2)	X				X				
	Contractors shall use Group CO (Contractual									
	Obligation) assigning financial liability to the									
	provider, if a claim is received with a GZ									
	modifier indicating no signed ABN is on file.									
	(Part A only) MSN 15.19: "Local Coverage									
	Determinations (LCDs) help Medicare decide									
	what is covered. An LCD was used for your									
	claim. You can compare your case to the									
	LCD, and send information from your doctor if you think it could change our decision. Call									
	1-800-MEDICARE (1-800-633-4227) for a									
	copy of the LCD".									
	Spanish Version - Las Determinaciones									
	Locales de Cobertura (LCDs en inglés) le									
	ayudan a decidir a Medicare lo que está									
	cubierto. Un LCD se usó para su									
	reclamación. Usted puede comparar su caso con la determinación y enviar información de									
	su médico si piensa que puede cambiar									
	nuestra decisión. Para obtener una copia del									

Number	Requirement	Responsibility										
			A/B		D		Sha	red-		Other		
		N	MA(\mathbb{C}	M		Sys	tem				
					Е		aint					
		Α	В	Н		F	M	V	С			
				Н	M			M				
				Н	A	S	S	S	F			
					C	S						
	LCD, llame al 1-800-MEDICARE (1800-											
	633-4227).											
	NOTE: Due to system requirement, FISS has											
	combined messages 15.19 and 15.20 so that,											
	when used for the same line item, both											
	messages will appear on the same MSN.											
10205 04.2	Contractors shall deare slainer for CET'	17	17			v	v					
10295 - 04.2	Contractors shall deny claims for SET using CPT 93668 unless accompanied by one of the	X	X			X	X					
	following diagnosis codes:											
	following diagnosis codes.											
	I70.211 –right leg											
	I70.212 – left leg											
	I70.213 – bilateral legs											
	I70.218 – other extremity											
	170.218 – Other extremity											
	I70.311 – right leg											
	2, 3,6 2 2 2,6.11 20 6											
	I70.312 – left leg											
	I70.313 – bilateral legs											
	I70 219 other extremity											
	I70.318 – other extremity											
	I70.611 – right leg											
	0 - 20											
	I70.612 – left leg											
	I70.613 – bilateral legs											

Number	Requirement	Re	espo	nsi						
	•		A/E		D	T .	Sha	red-		Other
		N	MA	C	M		Sys			
		_	Ъ		Е		aint			
		A	В	H H	M	F	M	V M		
				H	A	_	S	S	F	
					C	S				
	I70.618 – other extremity									
	I70.711 – right leg									
	170.712 1 6.1									
	I70.712 – left leg									
	I70.713 – bilateral legs									
	I70.718 – other extremity									
	170.716 – other extremity									
10295 - 04.2.1	When denying a line-item on the claim per	X	X							
	requirement 10295-04.2 contractors shall use the following messages:									
	the following messages.									
	MSN 15.20: "The following policies NCD									
	20.35 were used when we made this									
	decision."									
	Spanish Version – "Las siguientes políticas									
	NCD 20.35 fueron utilizadas cuando se tomó									
	esta decisión."									
	CARC 167 – This (these) diagnosis (es) is									
	(are) not covered. Note: Refer to the 835									
	Healthcare Policy Identification Segment									
	(loop 2110 Service Payment Information REF), if present.									
	KLI'), ii present.									
	RARC N386 – "This decision was based on a									
	National Coverage Determination 20.35 (NCD). An NCD provides a coverage									
	determination as to whether a particular item									
	or service is covered. A copy of this policy is									
	available at									
	www.cms.gov/mcd/search.asp. If you do not									
	have web access, you may contact the									
	contractor to request a copy of the NCD."									

Number	Requirement	Responsibility									
	•		A/B MA(}	D M		Sys	red- tem		Other	
		A	В	Н	Е	F	aint M	aine V	ers C		
				H H	M A	I S	C S	M S	W F		
					С	S					
10295 - 04.2.1.1	Contractors shall use Group Code PR (Patient Responsibility) assigning financial liability to the beneficiary if a claim is received with a GA modifier indicating a signed ABN is on file. Contractors shall use Group CO (Contractual Obligation) assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file. (Continuation of BR 10295-04.2.1) (Part A only) MSN 15.19: "Local Coverage Determinations (LCDs) help Medicare decide what is covered. An LCD was used for your claim. You can compare your case to the LCD, and send information from your doctor if you think it could change our decision. Call 1-800-MEDICARE (1-800-633-4227) for a copy of the LCD".	X	X								
	Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación. Usted puede comparar su caso con la determinación y enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD, llame al 1-800-MEDICARE (1800- 633-4227). NOTE: Due to system requirement, FISS has combined messages 15.19 and 15.20 so that, when used for the same line item, both messages will appear on the same MSN.										
10295 - 04.3	Effective for line items on claims with dates of services on or after May 25, 2017,	X	X			X			X		

Number	Requirement	Re	espo	nsi						
			A/B MA(D M E		Sys	red- tem		Other
		A	В	H H H	M A C	F	M C S	V	С	
	contractors shall have the discretion to pay SET claims (CPT 93668) which exceed 36 sessions (up to 72 sessions) within 84 days from the date of the first session when the KX modifier is on the claim line.									
	NOTE: This edit shall be overridable.									
10295 - 04.3.1	CWF shall create a new line-item edit for CPT 93668 to reject claims when a beneficiary has reached 37 SET sessions within 84 days after the date of the first SET session and the KX modifier is not included on the claim line OR to reject any SET session provided after 84 days from the date of the first session and the KX modifier is not included on the claim line.	X	X			X			X	
	NOTE: This edit shall be overridable.									
10295 - 04.3.1.1	Contractors shall reject claims with CPT93668 which exceed 36 sessions within 84 days from the date of the first session when the KX modifier is not included on the claim line OR any SET session provided after 84 days from the date of the first session and the KX modifier is not included on the claim and use the following messages:	X	X							
	96- Non-covered charge(s). At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason [sic] Code, or Remittance Advice Remark Code that is not an ALERT.) Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.									
	N640 Exceeds number/frequency approved/allowed within time period.									
	Contractors shall use Group CO (Contractual Obligation) assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.									

Number	Requirement	Responsibility										
rumber	Acquirement		A/B MA(3	D M E		Sha Sys	tem		Other		
		A	В	H H H	M A C	F I	ı	V	С			
10295 - 04.3.1.2	Contractors shall deny/reject claim lines with CPT 93668 when sessions have reached 73 sessions and use messaging provided in 10295.04.3.2.	X	X									
10295 - 04.3.2	When denying a line-item on the claim per BR 10295-04.3.1, contractors shall use the following messages:	X	X									
	MSN 15.20: "The following policies NCD 20.35 were used when we made this decision."											
	Spanish Version – "Las siguientes políticas NCD 20.35 fueron utilizadas cuando se tomó esta decisión."											
	CARC 119: "Benefit maximum for this time period or occurrence has been reached."											
	RARC N386: "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD."											
	Group Code PR (Patient Responsibility) assigning financial responsibility to the beneficiary (if a claim is received with occurrence code 32 with or without a GA modifier or a claim-line is received with a GA modifier indicating a signed ABN is on file)											
10295 - 04.3.2.1	Continuation of BR 10295-04.3.2)	X	X									

Number	Requirement	Responsibility										
	•		A/B		D			red-		Other		
		N	/IA	\mathbb{C}	M E		_	tem aine				
		A	В	Н	E	F	M		C			
				Н	M		C	M	W			
				Н	A C	S S	S	S	F			
	Group Code CO (Contractual Obligation) assigning financial liability to the provider (if a claim line-item is received with a GZ modifier indicating no signed ABN is on file and occurrence code 32 is not present). (Part A only) MSN 15.19: "Local Coverage Determinations (LCDs) help Medicare decide what is covered. An LCD was used for your claim. You can compare your case to the LCD, and send information from your doctor					2						
	if you think it could change our decision. Call 1-800-MEDICARE (1-800-633-4227) for a copy of the LCD".											
	Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación. Usted puede comparar su caso con la determinación y enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD, llame al 1-800-MEDICARE (1800-633-4227).											
	NOTE: Due to system requirement, FISS has combined messages 15.19 and 15.20 so that, when used for the same line item, both messages will appear on the same MSN.											
10295 - 04.4	CWF shall reject to contractors claim lineitems for SET, CPT 93668, when sessions have reached 73 sessions with or without the KX Modifier present.					X			X			
10295 - 04.4.1	When denying a line-item on the claim per requirement 10295-04 contractors shall use the following messages:	X	X									
	CARC 119: "Benefit maximum for this time period or occurrence has been reached."											

Number	Requirement	R	espo	nsi						
- TUMINUT	Arcyan ement		A/B MA(}	D M E		Sha Sys	tem		Other
		A	В	H H H	M A C	F	M C S	V	С	
	RARC N386: "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD." Group Code PR (Patient Responsibility) assigning financial responsibility to the beneficiary (if a claim is received with occurrence code 32 with or without a GA modifier or a claim-line is received with a GA modifier indicating a signed ABN is on file)									
10295 - 04.4.1.1	(Continuation of BR 10295-04.4.1) Group Code CO (Contractual Obligation) assigning financial liability to the provider (if a claim line-item is received with a GZ modifier indicating no signed ABN is on file and occurrence code 32 is not present). (Part A only) MSN 15.19: "Local Coverage Determinations (LCDs) help Medicare decide what is covered. An LCD was used for your claim. You can compare your case to the LCD, and send information from your doctor if you think it could change our decision. Call 1-800-MEDICARE (1-800-633-4227) for a copy of the LCD". Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación. Usted puede comparar su caso con la determinación y enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD, llame al 1-800-MEDICARE (1800-633-4227).	X	X							

Number	Requirement	Responsibility									
			A/B MA(,	D M E		Sha Sys aint	tem		Other	
		A	В	H H H	M A C	F	M C S	V	C W F		
	MSN 15.20: "The following policies NCD 20.35 were used when we made this decision." Spanish Version – "Las siguientes políticas										
	NCD 20.35 fueron utilizadas cuando se tomó esta decisión."										
	NOTE: Due to system requirement, FISS has combined messages 15.19 and 15.20 so that, when used for the same line item, both messages will appear on the same MSN.										
10295 - 04.5	CWF shall determine the remaining SET sessions up to 72 sessions total. Session 1 through session 36 does not require the –KX modifier. Session 37 through 72 requires the -KX modifier.								X		
10295 - 04.5.1	The CWF determination, to parallel claims processing, shall include all applicable factors including:								X		
	Beneficiary Part B entitlement status										
	Beneficiary AUX file										
	Utilization rules										
10295 - 04.5.2	CWF shall update the determination when any changes occur to the beneficiary master data or claims data that would result in a change to the calculation.								X		
10295 - 04.5.3	CWF shall display the remaining SET sessions on all CWF provider query screens (HIQA, HIQH, ELGH, ELGA and HUQA).					X			X	MBD, NGD	
10295 - 04.5.4	The Multi-Carrier System Desktop Tool (MCSDT) shall display the remaining SET sessions in a format equivalent to the CWF HIMR screen(s).		X				X				

Number	Requirement	Responsibility																			
			A/B MAC		MAC									MAC		D M E		Shared- System Maintainers			Other
		A	В	H H	M	F I S S	M C S	M	_												
10295 - 04.6	CWF will create a utility to count the number of SET sessions already posted with Dates of Service on or after May 25, 2017 that has posted through July 2, 2018.								X												
10295 - 04.7	CWF shall not recalculate the initial date for out of sequence claims.								X												
10295 - 04.8	Contractors shall not research and adjust any SET claims (CPT 93668) paid more than 36 sessions in an 84-day period, or any SET claims paid beyond 84 days without the –KX modifier prior to the implementation of this change request. However, contractors may adjust claims bought to their attention.	X	X																		

III. PROVIDER EDUCATION TABLE

Number	Requirement		Responsibility					
			A/B MA(D M E	C E D			
		A	В	H H H	M A C	I		
10295 - 04.9	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/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 sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's 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					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref	Recommendations or other supporting information:
Requirement	
Number	

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): David Dolan, 410-786-3365 or David.Dolan@cms.hhs.gov (Coverage), William Ruiz, 410-786-9283 or William.Ruiz@cms.hhs.gov (Institutional Claims), Teira Canty, 410-786-1974 or Teira.Canty@cms.hhs.gov (Supplier Claims), Wanda Belle, 410-786-7491 or Wanda.Belle@cms.hhs.gov (Coverage), Yvette Cousar, 410-786-2160 or Yvette.Cousar@cms.hhs.gov (Professional Claims), Patricia. Brocato-Simons, 410-786-0261 or Patricia.BrocatoSimons@cms.hhs.gov (Coverage)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: 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.

ATTACHMENTS: 0

Medicare Claims Processing Manual Chapter 32 – Billing Requirements for Special Services

Table of Contents (Rev. 4049, Issued: 05-11-18)

Transmittals for Chapter 32

390-Supervised exercise therapy (SET) Symptomatic Peripheral Artery Disease

- 390.1 General Billing Requirements
- 390.2 Coding Requirements for SET
- 390.3 Special Billing Requirements for Institutional Claims
- 390.4 Common Working File (CWF) Requirements
- 390.5 Applicable Medicare Summary Notice (MSN), Remittance Advice Remark Codes (RARC) and Claim Adjustment Reason Code (CARC) Messaging

390 Supervised exercise therapy (SET) Symptomatic Peripheral Artery Disease (Rev. 4049, Issued: 05-11-18, Effective: 05-25-17, Implementation: 07-02-18)

Effective for claims with dates of service on or after May 25, 2017, the Centers for Medicare and Medicaid Services (CMS) will cover supervised exercise therapy (SET) for beneficiaries with intermittent claudication (IC) for the treatment of symptomatic peripheral artery disease (PAD). Up to 36 sessions over a 12 week period are covered if all of the following components of a SET program are met:

The SET program must:

- consist of sessions lasting 30-60 minutes comprising a therapeutic exercise-training program for PAD in patients with claudication;
- be conducted in a hospital outpatient setting, or a physician's office;
- be delivered by qualified auxiliary personnel necessary to ensure benefits exceed harms, and who are trained in exercise therapy for PAD; and
- be under the direct supervision of a physician (as defined in 1861(r)(1)) of the Social Security Act (the Act)), physician assistant, or nurse practitioner/clinical nurse specialist (as identified in 1861(aa)(5)) of (the Act) who must be trained in both basic and advanced life support techniques.

Beneficiaries must have a face-to-face visit with the physician responsible for PAD treatment to obtain the referral for SET. At this visit, the beneficiary must receive information regarding cardiovascular disease and PAD risk factor reduction, which could include education, counseling, behavioral interventions, and outcome assessments.

SET is non-covered for beneficiaries with absolute contraindications to exercise as determined by their primary attending physician. .

Please refer to the National Coverage Determinations Manual (Publication 100-03, Section 20.35) for more information.

390.1 General Billing Requirements (Rev. 4049, Issued: 05-11-18, Effective: 05-25-17, Implementation: 07-02-18)

Effective for claims with date of services on or after May 25, 2017, contractors shall pay claims for SET for beneficiaries with IC for the treatment of symptomatic PAD, with a referral from the physician responsible for PAD treatment.

Medicare Administrative Contractors (MACs) have the discretion to cover SET beyond 36 sessions over 12 weeks and may cover an additional 36 sessions over an extended period of time. Contractors shall accept the inclusion of the **KX** modifier on the claim line(s) as an attestation by the provider of the services that documentation is on file verifying that further treatment beyond the 36 sessions of SET over a 12 week period meets the requirements of the medical policy.

390.2 Coding Requirements for SET (Rev. 4049, Issued: 05-11-18, Effective: 05-25-17, Implementation: 07-02-18)

- *CPT 93668 Under Peripheral Arterial Disease Rehabilitation*
- ICD-10 Codes

170.211 -right leg

170.212 – left leg

170.213 – bilateral legs

I70.218 – other extremity

170.311 – right leg

I70.312 – left leg

170.313 – bilateral legs

170.318 – other extremity

170.611 – right leg

170.612 – left leg

I70.613 – bilateral legs

I70.618 – other extremity

I70.711 – right leg

I70.712 – left leg

I70.713 – bilateral legs

I70.718 – other extremity

390.3 Special Billing Requirements for Institutional Claims (Rev. 4049, Issued: 05-11-18, Effective: 05-25-17, Implementation: 07-02-18)

Contractors shall pay claims for SET services containing CPT code 93668 on Types of Bill (TOBs) 13X under OPPS and 85X based on reasonable cost.

Contractors shall pay claims for SET services containing CPT 93668 with revenue codes 096X, 097X, or 098X when billed on TOB 85X Method II based on 115% of the lesser of the fee schedule amount or the submitted charge.

390.4 Common Working File (CWF) Requirements (Rev. 4049, Issued: 05-11-18, Effective: 05-25-17, Implementation: 07-02-18)

CWF shall create a new edit for CPT 93668 to reject claims when a beneficiary has reached 36 SET sessions within 84 days after the date of the first SET session and the KX modifier is not included on the claim or to reject any SET session provided after 84 days from the date of the first session and the KX modifier is not included on the claim.

CWF shall determine the remaining SET sessions.

The CWF determination, to parallel claims processing, shall include all applicable factors including:

- Beneficiary entitlement status
- Beneficiary claims history
- Utilization rules

CWF shall update the determination when any changes occur to the beneficiary master data or claims data that would result in a change to the calculation.

CWF shall display the remaining SET sessions on all CWF provider query screens.

The Multi-Carrier System Desktop Tool (MCSDT) shall display the remaining SET sessions in a format equivalent to the CWF HIMR screen(s).

390.5 Applicable Medicare Summary Notice (MSN), Remittance Advice Remark Codes and Claim Adjustment Reason Code Messaging (Rev. 4049, Issued: 05-11-18, Effective: 05-25-17, Implementation: 07-02-18)

• Contractors shall deny claims for SET when services are provided on other than TOBs 13X and 85X using the following messages:

MSN 15.20: "The following policies NCD 20.35 were used when we made this decision."

Spanish Version – "Las siguientes políticas NCD 20.35 fueron utilizadas cuando se tomó esta decisión."

(Part A only) MSN 15.19: "Local Coverage Determinations (LCDs) help Medicare decide what is covered. An LCD was used for your claim. You can compare your case to the LCD, and send information from your doctor if you think it could change our decision. Call 1-800-MEDICARE (1-800-633-4227) for a copy of the LCD".

Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación. Usted puede comparar su caso con la determinación y enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD, llame al 1-800-MEDICARE (1800-633-4227).

Claim Adjustment Reason Code (CARC) 58:

"Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. NOTE: Refer to the 832 Healthcare Policy Identification Segment (loop 2110 Service payment Information REF), if present.

Remittance advice remark code (RARC) N386: This decision was based on a National Coverage Determination (NCD) 20.35. An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Contractors shall use Group Code CO (Contractual Obligation) assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.

• Contractors deny/reject claim lines for CPT 93668 without one of the diagnosis codes listed in 390.2 and use the following messages:

MSN 15.20: "The following policies NCD 20.35 were used when we made this decision."

Spanish Version – "Las siguientes políticas NCD 20.35 fueron utilizadas cuando se tomó esta decisión."

(Part A only) MSN 15.19: "Local Coverage Determinations (LCDs) help Medicare decide what is covered. An LCD was used for your claim. You can compare your case to the LCD, and send information from your doctor if you think it could change our decision. Call 1-800-MEDICARE (1-800-633-4227) for a copy of the LCD".

Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación. Usted puede comparar su caso con la determinación y enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD, llame al 1-800-MEDICARE (1800-633-4227).

CARC 167 – This (these) diagnosis(es) is (are) not covered. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC N386 – "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at

www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD."

Contractors shall use Group Code PR (Patient Responsibility) assigning financial liability to the beneficiary if a claim is received with a GA modifier indicating a signed ABN is on file.

Contractors shall use Group CO (Contractual Obligation) assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.

• Contractors shall reject claims with CPT 93668 which exceed 36 sessions within 84 days from the date of the first session when the KX modifier is not included on the claim line OR any SET session provided after 84 days from the date of the first session and the KX modifier is not included on the claim and use the following messages:

96- Non-covered charge(s). At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason [sic] Code, or Remittance Advice Remark Code that is not an ALERT.)

Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

N640 Exceeds number/frequency approved/allowed within time period.

Group Code CO (Contractual Obligation) assigning financial liability to the provider (if a claim line-item is received with a GZ modifier indicating no signed ABN is on file and occurrence code 32 is not present).

• Contractors shall deny/reject claim lines with CPT 93668 when sessions have reached 73 sessions using the following messages:

MSN 15.20: "The following policies NCD 20.35 were used when we made this decision."

Spanish Version – "Las siguientes políticas NCD 20.35 fueron utilizadas cuando se tomó esta decisión."

(Part A only) MSN 15.19: "Local Coverage Determinations (LCDs) help Medicare decide what is covered. An LCD was used for your claim. You can compare your case to the LCD, and send information from your doctor if you think it could change our decision. Call 1-800-MEDICARE (1-800-633-4227) for a copy of the LCD".

Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación. Usted puede comparar su caso con la determinación y enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD, llame al 1-800-MEDICARE (1800-633-4227).

CARC 119: "Benefit maximum for this time period or occurrence has been reached."

RARC N386: "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD."

Group Code PR (Patient Responsibility) assigning financial responsibility to the beneficiary (if a claim is received with occurrence code 32 with or without a GA modifier or a claim-line is received with a GA modifier indicating a signed ABN is on file)

Group Code CO (Contractual Obligation) assigning financial liability to the provider (if a claim line-item is received with a GZ modifier indicating no signed ABN is on file and occurrence code 32 is not present

• Contractors shall deny claim line-items for SET, CPT 93668, when sessions have reached 73 sessions with or without the KX Modifier present using the following messages:

MSN 15.20: "The following policies NCD 20.35 were used when we made this decision."

Spanish Version – "Las siguientes políticas NCD 20.35 fueron utilizadas cuando se tomó esta decisión."

(Part A only) MSN 15.19: "Local Coverage Determinations (LCDs) help Medicare decide what is covered. An LCD was used for your claim. You can compare your case to the LCD, and send information from your doctor if you think it could change our decision. Call 1-800-MEDICARE (1-800-633-4227) for a copy of the LCD".

Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación. Usted puede comparar su caso con la determinación y enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD, llame al 1-800- MEDICARE (1800-633-4227).

CARC 119: "Benefit maximum for this time period or occurrence has been reached."

RARC N386: "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD."

Group Code PR (Patient Responsibility) assigning financial responsibility to the beneficiary (if a claim is received with occurrence code 32 with or without a GA modifier or a claim-line is received with a GA modifier indicating a signed ABN is on file)

Group Code CO (Contractual Obligation) assigning financial liability to the provider (if a claim line-item is received with a GZ modifier indicating no signed ABN is on file and occurrence code 32 is not present).