

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1913	Date: February 5, 2010
	Change Request 6775

SUBJECT: Outpatient Intravenous Insulin Treatment (Therapy)

I. SUMMARY OF CHANGES: Effective December 23, 2009, CMS determines that the evidence is adequate to conclude that outpatient intravenous insulin therapy (OIVIT) does not improve health outcomes in Medicare beneficiaries and is not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act. Therefore, OIVIT and services comprising an OIVIT regimen are nationally non-covered by Medicare.

NEW / REVISED MATERIAL

EFFECTIVE DATE: DECEMBER 23, 2009

IMPLEMENTATION DATE: MARCH 8, 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	4/Table of Contents
N	4/320/Outpatient Intravenous Insulin Treatment (OIVIT)
N	4/320.1/HCPCS Coding for OIVIT
N	4/320.2/Medicare Summary Notices (MSNs), Reason Codes, and Remark Codes

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. 100-04	Transmittal: 1913	Date: February 5, 2010	Change Request: 6775
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SUBJECT: Outpatient Intravenous Insulin Treatment (Therapy)

EFFECTIVE DATE: DECEMBER 23, 2009

IMPLEMENTATION DATE: MARCH 8, 2010

I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) internally generated a request for a National Coverage Determination on Outpatient Intravenous Insulin Therapy (OIVIT). On December 23, 2009, CMS issued a non-coverage decision on the use of OIVIT.

B. Policy: Effective December 23, 2009, CMS determines that the evidence is adequate to conclude that OIVIT does not improve health outcomes in Medicare beneficiaries, is not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act, and services comprising an OIVIT regimen are nationally non-covered under Medicare.

NOTE: A new HCPCS code effective December 23, 2009, to be implemented with the April 2010 Integrated Outpatient Code Editor (IOCE) and Medicare Physician Fee Schedule Database (MPFSDB), was created for use with this non-coverage decision.

NOTE: Effective April 5, 2010, HCPCS code 99199, unlisted special service, procedure, or report, is no longer an appropriate code to be used for OIVIT. Effective April 5, 2010, HCPCS code 94681, exhaled air analysis CO₂, should not be used in conjunction with OIVIT or diabetes-related conditions (250.00-250.93). Claims billed with these CPT codes will be returned to provider/returned as unprocessable to be billed with new code G9147, Outpatient Intravenous Insulin Treatment (OIVIT) either pulsatile or continuous, by any means, guided by the results of measurements for: respiratory quotient; and/or, urine urea nitrogen (UUN); and/or, arterial, venous or capillary glucose; and/or potassium concentration.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
						F I S S	M C S	V M S	C W F		
6775.1	Effective for claims with dates of service on and after December 23, 2009, contractors shall be aware that OIVIT and services comprising an OIVIT regimen are nationally non-covered by Medicare. See Pub. 100-03, NCD Manual, section 40.7, and Pub. 100-04, Claims Processing Manual, chapter 4, section 320, for specific coverage and claims processing instructions.	X		X	X						
6775.2	Effective April 5, 2010, G9147 shall be used on claims	X		X	X					IOCE	

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	billing for non-covered OIVIT and any services comprising an OIVIT regimen										MPFSDB April 2010
6775.3	Effective April 5, 2010, HCPCS code 99199 shall not be used on claims billing for non-covered OIVIT and any services comprising an OIVIT regimen.	X		X	X						
6775.3.1	<p>Claims for non-covered OIVIT and any services comprising an OIVIT regimen billed with HCPCS code 99199 shall be returned to provider/returned as unprocessable using:</p> <p>Claims Adjustment Reason Code (CARC) 189: NOS or unlisted procedure code (CPT/HCPCS) was billed when there is a specific procedure code for this procedure/service.</p> <p>Remittance Advice Remark Code (RARC) N56: The procedure code billed is not correct/valid for the services billed or the date of service billed.</p> <p>RARC MA66: Missing/incomplete/invalid principal procedure code.</p>	X		X	X						
6775.4	Effective April 5, 2010, HCPCS code 94681 shall not be used on claims billing for non-covered OIVIT and any services comprising an OIVIT regimen OR for claims billing diabetes-related conditions 250.00-250.93.	X		X	X						
6775.4.1	<p>Claims for non-covered OIVIT and any services comprising an OIVIT regimen or claims billing diabetes-related conditions 250.00-250.93 billed with HCPCS code 94681 shall be returned to provider/returned as unprocessable using:</p> <p>CARC 11: The diagnosis is inconsistent with the procedure.</p> <p>RARC N56: The procedure code billed is not correct/valid for the services billed or the date of service billed.</p> <p>RARC MA66: Missing/incomplete/invalid principal procedure code.</p>	X		X	X						
6775.5	When denying claims for non-covered OIVIT and any services comprising an OIVIT regimen billed with CPT code G9147, contractors shall use:	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	<p>MSN 16.10: Medicare does not pay for these item(s) or service(s)</p> <p>CARC 96: Non-covered charge(s)</p> <p>CARC M51: Missing/Incomplete /Invalid Procedure Code(s)</p> <p>RARC N386: This decision was based on an 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 http://www.cms.hhs.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.</p>										
6775.6	For claims with dates of service between December 23, 2009, and April 5, 2010, contractors shall not search their files, but may go back and adjust claims that are brought to their attention.	X		X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6775.7	<p>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.</p> <p>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 one 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</p>	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	would benefit their provider community in billing and administering the Medicare program correctly.										

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:
	N/A

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

V. CONTACTS

Pre-Implementation Contact(s): Patricia Brocato-Simons, coverage, 410-786-0261, Patricia.BrocatoSimons@cms.hhs.gov, William Ruiz, institutional claims processing, 410-786-9283, William.Ruiz@cms.hhs.gov, Bridgitte Davis, Bridgitte.davis@cms.hhs.gov, 410-786-4573

Post-Implementation Contact(s): CMS ROs

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.

Medicare Claims Processing Manual

Chapter 4 - Part B Hospital

(Including Inpatient Hospital Part B and OPPTS)

Table of Contents *(Rev.1913, 02-05-10)*

320 – Outpatient Intravenous Insulin Treatment (OIVIT)

320.1 – HCPCS Coding for OIVIT

320.2 – Medicare Summary Notices (MSN), Reason Codes, and Remark Codes

320 – Outpatient Intravenous Insulin Treatment (OIVIT)
(Rev. 1913, Issued: 02-05-10, Effective: 12-23-09, Implementation: 03-08-10)

Effective for claims with dates of service on and after December 23, 2009, the Centers for Medicare and Medicaid Services (CMS) determines that the evidence is adequate to conclude that OIVIT does not improve health outcomes in Medicare beneficiaries. Therefore, CMS determines that OIVIT is not reasonable and necessary for any indication under section 1862(a)(1)(A) of the Social Security Act, and services comprising an OIVIT regimen are nationally non-covered.

See Pub. 100-03, Medicare National Coverage Determinations Manual, Section 40.7, Outpatient Intravenous Insulin Treatment (Effective December 23, 2009), for general information and coverage indications.

320.1 – HCPCS Coding for OIVIT
(Rev. 1913, Issued: 02-05-10, Effective: 12-23-09, Implementation: 03-08-10)

Effective April 5, 2010, HCPCS code G9147 is to be used on claims billing for non-covered OIVIT and any services comprising an OIVIT regimen.

NOTE: *Effective April 5, 2010, HCPCS codes 99199 or 94681 (with or without diabetes related conditions 250.00-250.93) are not to be used on claims billing for non-covered OIVIT and any services comprising an OIVIT regimen. Claims billing for HCPCS codes 99199 and 94681 for non-covered OIVIT are to be returned to provider/returned as unprocessable.*

320.2 – Medicare Summary Notices (MSN), Reason Codes, and Remark Codes
(Rev. 1913, Issued: 02-05-10, Effective: 12-23-09, Implementation: 03-08-10)

When returning non-covered OIVIT claims billed with HCPCS 99199 to provider/returning as unprocessable, contractors shall use:

Claims Adjustment Reason Code (CARC) 189: NOS or unlisted procedure code (CPT/HCPCS) was billed when there is a specific procedure code for this procedure/service,

Remittance Advice Remark Code (RARC) N56: The procedure code billed is not correct/valid for the services billed or the date of service billed, and,

RARC MA66: Missing/incomplete/invalid principal procedure code.

When returning non-covered OIVIT claims billed with HCPCS 94681 with or without diabetes-related conditions 250.00-250.93 to provider/returning as unprocessable, contractors shall use:

CARC 11: The diagnosis is inconsistent with the procedure,

RARC N56: The procedure code billed is not correct/valid for the services billed or the date of service billed, and,

RARC MA66: Missing/incomplete/invalid principal procedure code.

When denying claims for non-covered OIVIT and any services comprising an OIVIT regimen billed with HCPCS code G9147, contractors shall use:

MSN 16.10 - Medicare does not pay for these item(s) or service(s),

CARC 96: Non-covered charge(s),

CARC M51: Missing/Incomplete /Invalid Procedure Code(s), and,

RARC N386: This decision was based on an 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 <http://www.cms.hhs.gov/mcd/search.asp>. If you do not have web access, you may contact the contractor to request a copy of the NCD.