CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 117	Date: March 9, 2010
	Change Request 6775

Transmittal 114, dated February 22, 2010, is being rescinded and replaced by Transmittal 117. The only change is the implementation date from March 8, 2010, to April 5, 2010. All other information remains the same.

SUBJECT: Outpatient Intravenous Insulin Treatment (Therapy)

I. SUMMARY OF CHANGES: Effective December 23, 2009, CMS determines that the evidence does not support a conclusion that OIVIT improves health outcomes in Medicare beneficiaries. Therefore, 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 under Medicare when furnished pursuant to an OIVIT regimen.

This revision is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries,[contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions], quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD.

NEW/REVISED MATERIAL
EFFECTIVE DATE: DECEMBER 23, 2009
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	1/Table of Contents
N	1/40.7/Outpatient Intravenous Insulin Treatment (Effective December 23, 2009)

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. 100-03	Transmittal: 117	Date: March 9, 2010	Change Request: 6775

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SUBJECT: Outpatient Intravenous Insulin Treatment (Therapy)

EFFECTIVE DATE: DECEMBER 23, 2009
IMPLEMENTATION DATE: APRIL 5, 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 does not support a conclusion that OIVIT improves health outcomes in Medicare beneficiaries. Therefore, 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 under Medicare when furnished pursuant to an OIVIT regimen.

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), will be created for use with this non-coverage decision.

NOTE: The unlisted special service, procedure, or report code is no longer appropriate for use with OIVIT. The exhaled air analysis CO2 code should not be used in conjunction with OIVIT or diabetes-related conditions. Claims billed with these codes will be returned to provider/returned as unprocessable to be billed with the new G code, 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 MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
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 for any indication when furnished pursuant to an OIVIT regimen. See Pub. 100-03, NCD Manual, section 40.7, and Pub. 100-04, Claims Processing Manual, chapter 4, section 320, for specific	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	
	coverage and claims processing instructions.										

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	
6775.2	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 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 would benefit their provider community in billing and administering the Medicare program correctly.	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:
	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): N/A

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 National Coverage Determinations Manual

Chapter 1, Part 1 (Sections 10 – 80.12)

Coverage Determinations

Table of Contents
(Rev. 117, 03-09-10)

40.7 – Outpatient Intravenous Insulin Treatment (Effective December 23, 2009)

(Rev. 117, Issued: 03-09-10, Effective Date: 12-23-09; Implementation Date: 04-05-10)

A. General

The term outpatient intravenous (IV) insulin therapy (OIVIT) refers to an outpatient regimen that integrates pulsatile or continuous intravenous infusion of insulin via any means, guided by the results of measurement of:

- *respiratory quotient; and/or*
- *urine urea nitrogen (UUN); and/or*
- *arterial, venous, or capillary glucose; and/or*
- *potassium concentration; and*

performed in scheduled recurring periodic intermittent episodes.

This regimen is also sometimes termed Cellular Activation Therapy (CAT), Chronic Intermittent Intravenous Insulin Therapy (CIIT), Hepatic Activation Therapy (HAT), Intercellular Activation Therapy (iCAT), Metabolic Activation Therapy (MAT), Pulsatile Intravenous Insulin Treatment (PIVIT), Pulse Insulin Therapy (PIT), and *Pulsatile Therapy (PT).*

In OIVIT, insulin is intravenously administered in the outpatient setting for a variety of indications. Most commonly, it is delivered in pulses, but it may be delivered as a more conventional drip solution. The insulin administration is adjunctive to the patient's routine diabetic management regimen (oral agent or insulin-based) or other disease management regimen, typically performed on an intermittent basis (often weekly), and frequently performed chronically without duration limits. Glucose or other carbohydrate is available ad libitum (in accordance with patient desire).

B. Nationally Covered Indications

N/A

C. Nationally Non-Covered Indications

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 does not support a conclusion that OIVIT improves health outcomes in Medicare beneficiaries. Therefore, CMS has determined that OIVIT is not reasonable and necessary for any indication under section 1862(a)(1)(A) of the Social Security Act. Services comprising an OIVIT regimen are nationally non-covered under Medicare when furnished pursuant to an OIVIT regimen (see subsection A. above).

D. Other

Individual components of OIVIT may have medical uses in conventional treatment regimens for diabetes and other conditions. Coverage for such other uses may be determined by other local or national Medicare determinations, and do not pertain to OIVIT. For example, see Pub. 100-03, NCD Manual, Section 40.2, Home Blood Glucose Monitors, Section 40.3, Closed-loop Blood Glucose Control Devices (CBGCD), Section 190.20, Blood Glucose Testing, and Section 280.14, Infusion Pumps, as well as Pub. 100-04, Claims Processing Manual, Chapter 18, Section 90, Diabetics Screening.

(This NCD last reviewed December 2009.)