

<b>CMS Manual System</b>	Department of Health & Human Services (DHHS)
<b>Pub 100-03 Medicare National Coverage Determinations</b>	Centers for Medicare & Medicaid Services (CMS)
Transmittal 67	Date: APRIL 6, 2007
	Change Request 5530

**SUBJECT: Blood Brain Barrier Osmotic Disruption for Treatment of Brain Tumors**

**I. SUMMARY OF CHANGES:** Effective for claims with dates of service on and after March 20, 2007, CMS determines that the use of osmotic blood brain barrier disruption is not reasonable and necessary when it is used as part of a treatment regimen for brain tumors. This NCD does not alter in any manner the coverage of anti-cancer chemotherapy.

**NEW/REVISED MATERIAL**

**EFFECTIVE DATE: MARCH 20, 2007**

**IMPLEMENTATION DATE: May 7, 2007**

*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**

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
<b>R</b>	1/Table of Contents
<b>N</b>	1/110.20/Blood Brain Barrier Osmotic Disruption for Treatment of Brain Tumors (Effective March 20, 2007)

**III. FUNDING:**

**No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.**

**IV. ATTACHMENTS:**

**Business Requirements  
Manual Instruction**

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

# Attachment - Business Requirements

Pub. 100-03	Transmittal: 67	Date: April 6, 2007	Change Request: 5530
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**SUBJECT: Blood Brain Barrier Osmotic Disruption for Treatment of Brain Tumors**

**Effective Date: March 20, 2007**

**Implementation Date: May 7, 2007**

## I. GENERAL INFORMATION

**A. Background:** Medicare does not currently have an NCD for osmotic blood brain barrier disruption (BBBD) used as part of a treatment regimen for brain tumors. CMS accepted a formal request for non-coverage of BBBD used for this indication.

**B. Policy:** Effective for claims with dates of service on and after March 20, 2007, CMS determines that the use of osmotic blood brain barrier disruption is not reasonable and necessary when it is used as part of a treatment regimen for brain tumors. This NCD does not alter in any manner the coverage of anti-cancer chemotherapy.

## 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  M A C	F I	C A R R I E R	D M E R C	R H I	E D C	Shared-System Maintainers				OTHER	
									F I S S	M C S	V M S	C M S		
5530.1	Effective for claims with dates of service on and after March 20, 2007, CMS determines that the use of osmotic blood brain barrier disruption is not reasonable and necessary when it is used as part of a treatment regimen for brain tumors. The BBBD process includes all items and services necessary to perform the procedure, including hospitalization, monitoring, and repeated imaging procedures.	X		X	X									

## III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)												
		A / B  M A C	D M  M A C	F I	C A R R I E R	D M E R C	R H I	E D C	Shared-System Maintainers				OTHER	
									F I S S	M C S	V M S	C M S		
5530.2	A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MLNMMattersArticles/">http://www.cms.hhs.gov/MLNMMattersArticles/</a> shortly after the CR is released. You will receive	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	D M E R C	R H I	E D C	Shared-System Maintainers				OTHER
									F I S S	M C S	V M S	C M S	
	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.												

#### IV. SUPPORTING INFORMATION

**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:
5530.1	A new ICD-9 procedure code to non-cover BBBD will be announced in an upcoming release to be effective 10/1/07. However, no new instructions will accompany the release of this code.

**B. For all other recommendations and supporting information, use this space:**

#### V. CONTACTS

**Pre-Implementation Contact(s):** Tara Turner (coverage), 410-786-0180, [tara.turner@cms.hhs.gov](mailto:tara.turner@cms.hhs.gov), Pat Brocato-Simons (coverage), 410-786-0261, [patricia-brocato-simons@cms.hhs.gov](mailto:patricia-brocato-simons@cms.hhs.gov).

**Post-Implementation Contact(s):** Appropriate regional office

#### VI. FUNDING

**A. For Fiscal Intermediaries, Carriers, and the Durable Medical Equipment Regional Carrier (DMERC):**

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

**B. For Medicare Administrative Contractors (MAC):**

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts specified 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 2 (Sections 90 – 160.26) Coverage Determinations

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*(Rev. 67, 04-06-07)*

*110.20 - Blood Brain Barrier Osmotic Disruption for Treatment of Brain Tumors  
(Effective March 20, 2007)*

***110.20 - Blood Brain Barrier Osmotic Disruption for Treatment of Brain Tumors (Effective March 20, 2007)***

***(Rev. 67, Issued: 04-06-07; Effective Date: 03-20-07; Implementation Date: 05-07-07)***

***A. General***

***The blood brain barrier (BBB) of the central nervous system is characterized by tight junctions between vascular endothelial cells, which prevent or impede various naturally occurring and synthetic substances (including anti-cancer drugs) from entering brain tissue. The BBB may be partly responsible for the poor efficacy of chemotherapy for malignant primary or metastatic brain tumors.***

***The BBBD is the disruption of the tight junctions between the endothelial cells that line the capillaries in the brain accomplished by osmotic disruption, bradykinin or irradiation. Theoretically, disruption of the BBB may, in the treatment of brain tumors, increase the concentration of chemotherapy drugs delivered to the tumor and may prolong the drug-tumor contact time.***

***Osmotic disruption of the BBB is the most common technique used. Chemotherapeutic agents are given in conjunction with barrier disruption. The BBBD process includes all items and services necessary to perform the procedure, including hospitalization, monitoring, and repeated imaging procedures.***

***B. Nationally Covered Indications***

***N/A***

***C. Nationally Non-Covered Indications***

***Effective for services performed on and after March 20, 2007, the Centers for Medicare & Medicaid Services determines that the use of osmotic BBBD is not reasonable and necessary when it is used as part of a treatment regimen for brain tumors.***

***D. Other***

***This NCD does not alter in any manner the coverage of anti-cancer chemotherapy.***

***(This NCD last reviewed March 2007.)***