

Local Coverage Article: Treatment with Yttrium-90 Microspheres (A54071)

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California - Entire State American Samoa Guam
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada American Samoa California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01911 - MAC A	J - E	Guam Hawaii Nevada Northern Mariana Islands

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Article Information

General Information

Article ID
A54071

Original ICD-9 Article ID
[A52207](#)

Article Title
Treatment with Yttrium-90 Microspheres

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10/01/2015

Revision Effective Date
N/A

Revision Ending Date
N/A

Retirement Date
N/A

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Article Guidance

Article Text:

Noridian receives requests for coverage of the treatment of various conditions with yttrium-90 microspheres. If all requirements of the Federal Drug Administration's (FDA) Premarket Approval (PMA) approved indications (full approval based on safety and efficacy), use of yttrium microspheres will be covered. If the treatment indication is under study with an Investigation Device Exemption (IDE), submit an application for (IDE) study coverage.

- **JF Part A:** https://www.noridianmedicare.com/parta/forms/mr_forms/fda_approved_ide_mac.pdf.
- **JF Part B:** https://www.noridianmedicare.com/partb/forms/mr_forms/fda_approved_ide_mac.pdf.

If the product has FDA Humanitarian Device Exemption (HDE) approval (reasonable safety but efficacy not demonstrated), submit the claim for payment, noting the HDE number in Item 19 of the 1500 Claim Form or the electronic equivalent for Part B billings. If the claim is denied, appeal and request a Contractor Medical Director (CMD) review. For additional information, see the Noridian article titled "Humanitarian Use Devices and Humanitarian Device Exemptions."

Background: At the current time there are two companies that manufacture and sell yttrium-90 microspheres in the USA: Sirtex and MDS Nordion.

• Sirtex

- o Sirtex manufactures resin microspheres called SIR-Spheres®. This product is FDA-approved for the treatment of colorectal metastases (mCRC) to the liver when the liver tumors are unresectable.
- o There is a RCT study in the USA called SIRFLOX, involving SIR-Spheres® (under an IDE) in combination with FOLFOX6 +/- Avastin as a first line treatment for patients with metastatic colorectal cancer (mCRC).

• MDS Nordion

- o MDS Nordion manufactures glass microspheres called TheraSphere®. TheraSphere® has HDE approval from the FDA for the treatment of hepatocellular cancer (HCC) for use in "radiation treatment or as a neoadjuvant to surgery or transplantation in patients with unresectable hepatocellular carcinoma (HCC) who can have placement of appropriately positioned hepatic arterial catheters.
- o The device is also indicated for HCC patients with partial or branch portal vein thrombosis/occlusion, when clinical evaluation warrants the treatment."
- o Nordion has opened IDE studies for use of the product in the treatment of unresectable advanced HCC if the patient is not eligible for any curative procedures and for whom standard-of-care therapy with sorafenib is planned.

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Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the article, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the article should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes

Group 1 Paragraph:

Coding Information:

Providers are instructed to bill Q3001 when using either SIR-Spheres or TheraSpheres in a non-OPPS facility setting. Providers must place the name of the device and invoice price in Item 19 of the CMS 1500 Claim Form or the electronic equivalent or the claim will be denied for Part B billings.

Group 1 Codes:

Group 1 CPT/HCPCS Code

Group 1 CPT/HCPCS Code Description

C2616	BRACHYTHERAPY SOURCE, NON-STRANDED, YTTRIUM-90, PER SOURCE
Q3001	RADIOELEMENTS FOR BRACHYTHERAPY, ANY TYPE, EACH

ICD-10 Codes that are Covered

Group 1 Paragraph:

Manufacturer: Sirtex Medical

Brachytherapy device name: SIR-Spheres®

FDA status:

Full PMA approval for mCRC

IDE for mCRC (+FOLFOX6+Avastin)

Particle: Resin particle with Y-90

HCPCS Code: C2616

ICD-10 **C78.7 and 1)** either a diagnosis from Group 1 or Group 2 (or both).

Group 1

Group 1 Codes:

ICD-10 Codes that are covered Information Table

Code	Description
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon
C18.9	Malignant neoplasm of colon, unspecified

Group 2 Paragraph:

Group 2

Group 2 Codes:

ICD-10 Codes that are covered Information Table

Code	Description
C19	Malignant neoplasm of rectosigmoid junction

Code	Description
C20	Malignant neoplasm of rectum
C21.0	Malignant neoplasm of anus, unspecified
C21.1	Malignant neoplasm of anal canal
C21.2	Malignant neoplasm of cloacogenic zone
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal

Group 3 Paragraph:
OR 2) ICD-10 C78.7 and

Group 3 Codes:

ICD-10 Codes that are covered Information Table

Code	Description
Z85.038	Personal history of other malignant neoplasm of large intestine

Group 4 Paragraph:

Manufacturer: MDS Nordion

Brachytherapy device name: TheraSphere®

FDA status:

HDE for HCC

IDE for HCC (+ Sorafenib)

Particle: Glass matrix with Y-90

HCPCS Code: C2616

Group 4 Codes:

ICD-10 Codes that are covered Information Table

Code	Description
C22.0	Liver cell carcinoma

ICD-10 Codes that are Not Covered N/A

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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation
10/01/2015	R1	Dual diagnostic criteria is added when billing for SIR-Spheres®.

[Back to Top](#) **Related Local Coverage Document(s)** N/A

Related National Coverage Document(s) N/A

Statutory Requirements URL(s) N/A

Rules and Regulations URL(s) N/A

CMS Manual Explanations URL(s) N/A

Other URL(s) N/A

Public Version(s) Updated on 02/25/2015 with effective dates 10/01/2015 - N/A [Back to Top](#)

Keywords

- Sirtex
- Nordion
- TheraSphere

- SIR-Spheres
- HDE
- Humanitarian Device Exemption
- brachytherapy

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