

Local Coverage Article: Billing and Coding: Treatment with Yttrium-90 Microspheres (A54072)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

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
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01911 - MAC A	J - E	American Samoa California - Entire State Guam Hawaii Nevada Northern Mariana Islands

Article Information

General Information

Article ID

A54072

Original Effective Date

10/01/2015

Article Title

Billing and Coding: Treatment with Yttrium-90
Microspheres

Revision Effective Date

04/12/2018

Article Type

Billing and Coding

Revision Ending Date

N/A

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

CPT codes, descriptions and other data only are copyright 2019 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply.

Retirement Date

N/A

Current Dental Terminology © 2019 American Dental Association. All rights reserved.

Copyright © 2019, the American Hospital Association, Chicago, Illinois. Reproduced with permission. No portion of the AHA copyrighted materials contained within this publication may be copied without the express written consent of the AHA. AHA copyrighted materials including the UB-04 codes and descriptions may not be removed, copied, or utilized within any software, product, service, solution or derivative work without the written consent of the AHA. If an entity wishes to utilize any AHA materials, please contact the AHA at 312-893-6816. Making copies or utilizing the content of the UB-04 Manual, including the codes and/or descriptions, for internal purposes, resale and/or to be used in any product or publication; creating any modified or derivative work of the UB-04 Manual and/or codes and descriptions; and/or making any commercial use of UB-04 Manual or any portion thereof, including the codes and/or descriptions, is only authorized with an express license from the American Hospital Association. To license the electronic data file of UB-04 Data Specifications, contact Tim Carlson at (312) 893-6816 or Laryssa Marshall at (312) 893-6814. You may also contact us at ub04@healthforum.com.

CMS National Coverage Policy

N/A

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.

Coding Information

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:

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

CPT/HCPCS Modifiers

N/A

ICD-10 Codes that Support Medical Necessity

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 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 CODE	DESCRIPTION
C19	Malignant neoplasm of rectosigmoid junction
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 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 CODE	DESCRIPTION
C22.0	Liver cell carcinoma

ICD-10 Codes that DO NOT Support Medical Necessity

N/A

Additional ICD-10 Information

N/A

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 policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy 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 policy, 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 policy should be assumed to apply equally to all Revenue Codes.

N/A

Other Coding Information

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
04/12/2018	R3	As required by CR 10901, article is converted to a formal billing and coding type article. There is no change in coverage.
04/12/2018	R2	This article effective 4/12/2018, combines JEA A54071 in JEB A54072 so that both JEA and JEB Contract numbers will have the same final MCD Article number A54072.
09/15/2014	R1	Dual diagnostic criteria is added when billing for SIR-Spheres®.

Associated Documents

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 05/07/2020 with effective dates 04/12/2018 - N/A

Updated on 04/02/2018 with effective dates 04/12/2018 - N/A

Updated on 02/25/2015 with effective dates 10/01/2015 - N/A

Keywords

N/A