

A person is shown in profile, looking at a computer monitor. The monitor displays a medical scan, likely a CT scan of a head, with a red outline highlighting a specific area. The background is blurred, showing an office or clinical setting. The text is overlaid on a blue banner at the bottom of the image.

**Simplicit<sup>90Y</sup>™**  
**Personalized Dosimetry Software**  
**2024 Coding & Payment Guide**



# Simplicit<sup>90</sup>Y™ 2024 Coding Guide with FAQs and Medicare Allowable Reimbursement

These products can only be used by licensed healthcare professionals. Caution: Federal law restricts this device to sale by or on the order of a physician. Additional important safety information about the above products is available at [Simplicit90Y](#). Please review if you intend to use these products.

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# Coding and Medicare 2024 Allowable Reimbursement

## Brachytherapy Clinical Treatment Planning and Basic Dosimetry

### PHYSICIAN SERVICES

Service Provided		Physician Fee Schedule		
CPT® Code	CPT® Description	RVUs	Facility	Non Facility
77300a	Basic dosimetry calc, CADD calc, TDF, NSD, Gap calc, OAF, TIF, NIRSDD calc (req Rx	0.62	\$32	\$65
77316a	Brachytherapy Isodose Plan, 1-4 Sources, Incl Basic Dosimetry Calc	1.40	\$72	\$242

### OPPS PROCEDURAL SERVICES

Service Provided		Hospital Outpatient		
CPT® Code	CPT® Description	Status Indicator	APC	Payment
77300	Basic dosimetry calc, CADD calc, TDF, NSD, Gap calc, OAF, TIF, NIRSDD calc (req Rx treat phys)	S	5611	\$129
77316	Brachytherapy Isodose Plan, 1-4 Sources, Incl Basic Dosimetry Calc	S	5612	\$352

### ASC PROCEDURAL SERVICES

Service Provided		ASC	
CPT® Code	CPT® Description	Status Indicator	Payment
77300	Basic dosimetry calc, CADD calc, TDF, NSD, Gap calc, OAF, TIF, NIRSDD calc (req Rx treat phys)	Z3	\$33
77316	Brachytherapy Isodose Plan, 1-4 Sources, Incl Basic Dosimetry Calc	Z3	\$169



The Current Procedural Terminology (CPT) code below may be considered when using Simplicit90Y to create a 3-D Clinical Treatment Plan for [TheraSphere™ Y-90 Glass Microspheres](#) therapy, including reconstruction of tumor volume(s), surrounding structures, BEV (Beam's Eye View), dose-volume histograms, and 3-D dose clouds.

**PHYSICIAN SERVICES**

Service Provided		Physician Fee Schedule		
CPT® Code	CPT® Description	RVUs	Facility	Non Facility
77295b	3-dimensional radiotherapy plan, including dose-volume histograms	4.29	\$219	\$472

**OPPS PROCEDURAL SERVICES**

Service Provided		Hospital Outpatient		
CPT® Code	CPT® Description	Status Indicator	APC	Payment
77295	3-dimensional radiotherapy plan, including dose-volume histograms	S	5613	\$1,322

**ASC PROCEDURAL SERVICES**

Service Provided		ASC	
CPT® Code	CPT® Description	Status Indicator	Payment
77295	3-dimensional radiotherapy plan, including dose-volume histograms	Z3	\$250



## NOTES

**NOTE:** When performing procedures requiring moderate sedation (CPT 99152, 99153) and billing on the same DOS as CPT 77263, 77290, 77295, 77300, 77316, 77317, 77331, 77370, 77470, 77778, and 77790, an NCCI-associated modifier such as -59, -XP, or -XU must be applied to the moderate sedation codes.

### OPPS Status Indicators

**S:** Procedure or Service not discounted when multiple.

### ASC Status Indicators

**Z3:** Radiology or diagnostic service paid separately when provided integral to a surgical procedure on ASC list; payment based on MPFS non-facility PE RVUs.

NCCI edit bundles CPT 77300 with CPT 77316-77318, 77331, and 77778 on same DOS.

NCCI edit bundles CPT 77290 and CPT 77316-77318 into CPT 77295 on same DOS.

Physician charges for professional component of procedure, modifier -26.

The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.

## SOURCES

### PHYSICIAN SERVICES

2024 Physician Fee Schedule. CMS-1784-F [PFS Federal Regulation Notices | CMS](#)

2024 *Conversion Factor of \$32.7442*

### OPPS PROCEDURAL SERVICES

2024 OPPS Payment. CMS-1786-FC. <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice/cms-1786-fc>

### ASC PROCEDURAL SERVICES

2024 ASC Payment. CMS-1786-FC. <https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and/cms-1786-fc>

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## Simplicit<sup>90</sup>Y™ Intended Use

Simplicit<sup>90</sup>Y is intended to be used by trained medical professionals for TheraSphere™ pre-treatment dosimetry planning and post-treatment dosimetry evaluation following Y-90 treatment.

Simplicit<sup>90</sup>Y is a medical image and information management system that is intended to receive, transmit, store, retrieve, display, and process digital medical images, as well as create, display and print reports from those images. The medical modalities of these medical imaging systems include, but are not limited to, CT, MRI, SPECT, and PET.

Simplicit<sup>90</sup>Y provides the user with the means to display, register and fuse medical images from multiple modalities.

Simplicit<sup>90</sup>Y provides tools to create, transform, and modify contours for the user to define objects in medical image volumes for use in TheraSphere pre-treatment dosimetry planning and for post-treatment dosimetry. The objects include, but are not limited to, tumors and normal tissues.

## Simplicit<sup>90</sup>Y Indications for Use

Simplicit<sup>90</sup>Y is a standalone software device that is used by trained medical professionals as a tool to aid in evaluation and information management of digital medical images.

Simplicit<sup>90</sup>Y supports the reading, rendering and display of a range of DICOM compliant imaging and related formats including but not limited to CT, PT, NM, SPECT, MR, SC, RTSS. Simplicit<sup>90</sup>Y enables the saving of sessions in a proprietary format as well as the export of formats including CSV and PDF files.

Simplicit<sup>90</sup>Y is indicated, as an accessory to TheraSphere, to provide pre-treatment dosimetry planning support including Lung Shunt Fraction estimation (based on planar scintigraphy) and liver single-compartment MIRD schema dosimetry, in accordance with TheraSphere labelling. Simplicit<sup>90</sup>Y provides tools to create, transform, and modify contours/Regions of Interest for calculation of Lung Shunt Fraction and Perfused Volume. Simplicit<sup>90</sup>Y includes features to aid in TheraSphere dose vial selection, dose vial ordering and creation of customizable reports.

Simplicit<sup>90</sup>Y is indicated for post-treatment dosimetry and evaluation following Yttrium-90 (Y-90) microsphere treatment. Simplicit<sup>90</sup>Y provides tools to create, transform, and modify contours/Regions of Interest for the user to define objects in medical image volumes to support TheraSphere post-Y-90 treatment calculation and evaluation. The objects include, but are not limited to, tumors and normal tissues, and liver volumes.

Simplicit<sup>90</sup>Y is indicated for registration, fusion display and review of medical images allowing medical professionals to incorporate images, such as CT, MRI, PET, CBCT and SPECT in TheraSphere Yttrium-90 (Y-90) microspheres pre-treatment planning and post-Y-90 treatment evaluation.

For post-Yttrium-90 (Y-90) treatment, Simplicit<sup>90</sup>Y should only be used for the retrospective determination of dose and should not be used to prospectively calculate dose or for the case where there is a need for retreatment using Y-90 microspheres.

***Simplicit<sup>90</sup>Y dosimetry planning and confirmation software is manufactured by Mirada Medical Ltd. and designed in collaboration with Boston Scientific Corporation. Simplicit<sup>90</sup>Y is a registered trademark of Boston Scientific Corporation.***





## About TheraSphere™ Y-90 Glass Microspheres

TheraSphere consists of insoluble glass microspheres where yttrium-90 is an integral constituent of the glass. The product is injected by a physician into an artery of the patient's liver through a catheter, which allows the treatment to be delivered directly to the tumor via blood flow. The microspheres, being unable to pass through the vasculature of the liver due to arteriolar capillary blockade, are trapped in the tumor and exert a local radiotherapeutic effect with some concurrent damage to surrounding normal liver tissue.

In the United States, TheraSphere is indicated for use as selective internal radiation therapy (SIRT) for local tumor control of solitary tumors (1-8 cm in diameter), in patients with unresectable hepatocellular carcinoma (HCC), Child-Pugh Score A cirrhosis, well-compensated liver function, no macrovascular invasion, and good performance status.

TheraSphere is approved by the US Food and Drug Administration (FDA) under a premarket approval (PMA) **P200029**. PMA is the most stringent type of device marketing application required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).<sup>1</sup> The FDA provides PMA guidance on the clinical data accepted to support medical device applications and submissions.<sup>2</sup> TheraSphere requires a Radioactive Material License (RAML)<sup>3</sup> for use, and it must be used in accordance with US Nuclear Regulatory Commission (NRC) or state requirements.<sup>4</sup> Boston Scientific has notified the NRC of the PMA and has requested an update to the Microsphere Licensing Guidance<sup>3</sup> to eliminate references to the previous product approval which was under a Humanitarian Device Exemption.

The Instructions for Use (IFU), Warnings and Precautions may be found on the Boston Scientific eLabeling website: <https://www.bostonscientific.com/elabeling/us/en/home/healthcare-professionals.html>. Search for key word **TheraSphere** to locate it. The options should appear after typing the first 3 letters.

## ICD-10 CM Diagnosis Codes

Primary diagnosis

**C22.0** Liver cell carcinoma; Hepatocellular carcinoma; Hepatoma

<sup>1</sup> FDA. Premarket approval (PMA). <https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma>. Accessed December 29, 2021.

<sup>2</sup> FDA. Acceptance of Clinical Data to Support Medical Device Applications and Submissions: FAQ. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-clinical-data-support-medical-device-applications-and-submissions-frequently-asked>. Accessed December 29, 2021.

<sup>3</sup> NRC. Yttrium-90 Microsphere Brachytherapy Sources and Devices - TheraSphere® and SIR-Spheres® Licensing Guidance Rev 10.2. <https://www.nrc.gov/docs/ML2108/ML21089A364.pdf>. Accessed December 29, 2021.

<sup>4</sup> NRC. Part 35-medical use of byproduct material. <https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/full-text.html>. Accessed December 29, 2021.