



Simplicit⁹⁰Y™

Personalized Dosimetry Software

2025 Coding & Payment Guide



Simplicit⁹⁰Y™ 2025 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.

Claims must contain the appropriate HCPCS/CPT/ICD-10 code(s) for the specific site of service to indicate the items and services that are furnished. The tables below contain a list of possible HCPCS/CPT/ICD-10 codes that may be used to bill for Simplit⁹⁰Y™. Providers should select the most appropriate code(s) and modifier(s) with the highest level of detail to describe the service(s) actually rendered. CPT © Copyright 2024 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

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Coding and Medicare 2025 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, NIRSDC calc (req Rx	0.62	\$32	\$65
77316a	Brachytherapy Isodose Plan, 1-4 Sources, Incl Basic Dosimetry Calc	1.40	\$72	\$241

CPT Codes are used to report medical services and procedures performed by or under the direction of physicians in the office or facility setting. The MPFS is based on Relative Value Units (RVUs) assigned to each CPT code. RVUs represent the physician's work, practice expenses and malpractice costs associated with each procedure or service. Reimbursement for commercial payers may be based on the Medicare RVUs or by a contractually negotiated rate.

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, NIRSDC calc (req Rx treat phys)	S	5611	\$133
77316	Brachytherapy Isodose Plan, 1-4 Sources, Incl Basic Dosimetry Calc	S	5612	\$366

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, NIRSDC calc (req Rx treat phys)	Z3	\$33
77316	Brachytherapy Isodose Plan, 1-4 Sources, Incl Basic Dosimetry Calc	Z3	\$168



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	\$220	\$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	\$1,368

ASC PROCEDURAL SERVICES

Service Provided		ASC	
CPT® Code	CPT® Description	Status Indicator	Payment
77295	3-dimensional radiotherapy plan, including dose-volume histograms	Z3	\$249



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

1. 2025 Physician Fee Schedule. CMS-1807-F. <https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices/cms-1807-f>
2025 Conversion Factor of \$32.3465
2. 2025 OPPS Payment. CMS-1809-FC. <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1809-fc>
3. 2025 ASC Payment. CMS-1809-FC. <https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and/cms-1809-fc>



Simplicit90Y™ Intended Use

Simplicit90Y is intended to be used by trained medical professionals for TheraSphere™ pre-treatment dosimetry planning and post-treatment dosimetry evaluation following Y-90 treatment.

Simplicit90Y 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.

Simplicit90Y provides the user with the means to display, register and fuse medical images from multiple modalities.

Simplicit90Y 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.

Simplicit90Y Indications for Use

Simplicit90Y 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.

Simplicit90Y 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. Simplicit90Y enables the saving of sessions in a proprietary format as well as the export of formats including CSV and PDF files.

Simplicit90Y 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. Simplicit90Y provides tools to create, transform, and modify contours/Regions of Interest for calculation of Lung Shunt Fraction and Perfused Volume. Simplicit90Y includes features to aid in TheraSphere dose vial selection, dose vial ordering and creation of customizable reports.

Simplicit90Y is indicated for post-treatment dosimetry and evaluation following Yttrium-90 (Y-90) microsphere treatment. Simplicit90Y 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.

Simplicit90Y 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, Simplicit90Y 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.

Simplicit90Y dosimetry planning and confirmation software is manufactured by Mirada Medical Ltd. and designed in collaboration with Boston Scientific Corporation. Simplicit90Y 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).¹ The FDA provides PMA guidance on the clinical data accepted to support medical device applications and submissions.² TheraSphere requires a Radioactive Material License (RAML)³ for use, and it must be used in accordance with US Nuclear Regulatory Commission (NRC) or state requirements.⁴ Boston Scientific has notified the NRC of the PMA and has requested an update to the Microsphere Licensing Guidance³ 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

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

² 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.

³ 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.

⁴ 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.