

Brachytherapy



INDEPENDENT CARE HEALTH PLAN

Medicare Advantage Medical Coverage Policy

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to [CMS website](#) for the most current applicable National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

Type	Title	ID Number	Jurisdiction Medicare Administrative	Applicable States/Territories
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			Contractors (MACs)	
LCD LCA	Category III Codes	L35490 A56902	J5 - Wisconsin Physicians Service Insurance Corporation	AL, AK, AZ, AR, CA, CO, CT, DE, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY
			J8 - Wisconsin Physicians Service Insurance Corporation	IN, MI
LCA	Billing and coding: percutaneous coronary interventions	A57479	J5 - Wisconsin Physicians Service Insurance Corporation	AL, AK, AZ, AR, CA, CO, CT, DE, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY
			J8 - Wisconsin Physicians Service Insurance Corporation	IN, MI
LCA	Billing and coding: treatment with Yttrium-90 microspheres	A54072	JE - Noridian Healthcare Solutions, LLC	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands
LCA	Billing and coding: treatment with Yttrium-90 microspheres	A52950	JF - Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
LCD LCA	Prostate Rectal Spacers	L37485	J6 - National Government Services, Inc. (Part A/B MAC)	IL, MN, WI

		A56539	JK - National Government Services, Inc. (Part A/B MAC	CT, NY, ME, MA, NH, RI, VT
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Description

Brachytherapy, also known as internal radiation therapy, is a treatment in which radioactive sources are placed inside an individual either temporarily (via a catheter or tube for a specific time and withdrawn) or permanently (seeds or pellets in or near the tumor which are not removed). Brachytherapy can be used to treat cancer throughout the body. Brachytherapy can also be utilized to prevent intracoronary restenosis after stent placement. Based on the technique, either high-dose rate (HDR) or low-dose rate (LDR) brachytherapy can be utilized.

There are two main types of brachytherapy, which include intracavity and interstitial. Intracavity treatment involves the placement of a radioactive source in the body cavity near the tumor (eg, cervix, trachea, vagina) and interstitial treatment is performed by placing the radioactive source in the form of seeds, pellets or sheets directly into or around the tissue. Examples of interstitial radiation therapy include, but may not be limited to, **CivaSheet** (eg, prostate cancer) or **GammaTile** (eg, brain tumors). Another type of treatment is surface brachytherapy (may also be known as plaque brachytherapy), which is performed when the radiation sources are placed directly on an external tumor or target surface (eg, eye, skin cancer).

Brachytherapy can be delivered using several methods including, but may not be limited to:

- **Breast brachytherapy** treatment delivers radiation via a balloon catheter following a lumpectomy to the space left after the cancerous tumor is removed and to the tissue directly surrounding the cavity. By delivering radiation to the area directly surrounding the original tumor, radiation exposure is minimized to the rest of the breast and other organs. Examples of delivery systems include, but may not be limited to, the **CONTURA Multi-Lumen Balloon (MLB) Catheter**, **MammoSite Radiation Therapy System (RTS)**, the and the **SAVI applicator**, which is a single-entry device that allows physicians to customize radiation treatments based on individual-specific anatomy.
- **Electronic brachytherapy (EBT)** is radiotherapy uses an HDR, low-energy X-ray source to apply brachytherapy to the cancerous site. Purportedly, EBT is utilized to provide intracavity, interstitial or surface brachytherapy. EBT is being studied for use during intraoperative radiation therapy (IORT) for brain tumors. Following surgical removal of the tumor and the placement of a radiation therapy applicator into the tumor cavity, EBT is reportedly delivered directly to the tumor bed. Examples of EBT devices include, but may not be limited to, the **Xoft Axxent Electronic Brachytherapy System**, the **Esteya EBT system** and the **INTRABEAM system**.
- **Intracoronary brachytherapy** is used to prevent restenosis of an artery after angioplasty or stent placement by delivering a small amount of radiation to the treated area, which may reduce the need for additional angioplasty or bypass surgery. The radiation is intended to discourage the overgrowth of normal tissue as the healing process occurs.

- **Intravascular brachytherapy** has been investigated as an adjunct to angioplasty of the femoropopliteal segment to reduce the risk of restenosis.
- **Noninvasive brachytherapy** of the breast involves the use of mammography, which reportedly provides real-time images of the lumpectomy cavity and identifies the size and location needed for the dosing applicators. Noninvasive HDR brachytherapy applicators are positioned on opposite sides of the breast and radiation is delivered directly to the target site. An example of a noninvasive brachytherapy device is the **Accuboot system**.
- **Selective internal radiation therapy (SIRT)**, also known as radioembolization, is a procedure in which tiny radiation-filled beads (eg, yttrium-90), called microspheres, are delivered directly to the tumor. The microspheres are delivered through a catheter placed in the femoral artery and threaded through the hepatic artery to the tumor site. Examples of this type of treatment include, but may not be limited to:
 - **SIR-Spheres** are resin spheres that are indicated for the treatment of unresectable metastatic liver tumors from primary colorectal cancer (CRC).
 - **Theraspheres** are spheres made of glass, which are indicated for unresectable primary hepatocellular carcinoma (HCC).

The placement of a **transperineal biodegradable spacer** also known as **prostate rectal spacers (eg, Barrigel, SpaceOAR, SpaceOAR Vue)** positions the anterior (frontal) section of the rectal wall away from the prostate during external beam radiotherapy treatments for prostate cancer with the goal of limiting the radiation exposure to the anterior rectum. Because this material is biodegradable, it is absorbed over time by the individual's body. SpaceOAR is comprised of a synthetic, absorbable polyethylene glycol-based hydrogel. SpaceOAR Vue contains PEGylated iodine, which is designed to enhance visibility via CT scan. Barrigel injectable gel is similar to the SpaceOAR product; however, it is made of stabilized hyaluronic acid.

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

Please refer to the above CMS guidance for use of **brachytherapy for percutaneous coronary interventions** and **electronic brachytherapy (category III codes)**.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the criteria contained in the following:

Brachytherapy will be considered medically reasonable and necessary when the following requirements are met:

- Breast cancer:
 - Accelerated partial breast irradiation (APBI) when the following indications are met^{22,64,89}:
 - 50 years of age or older; **AND**
 - Invasive carcinoma or ductal carcinoma in situ (DCIS); **AND**
 - Node negative; **AND**
 - Total tumor size less than or equal to 2 cm⁶⁴; **AND**
 - Tumor removed with negative surgical margins; **OR**
 - Adjunctive boost to the tumor bed in an individual receiving whole breast radiation therapy (WBRT) following breast conserving surgery (eg, lumpectomy)⁸⁹; **OR**
- Cholangiocarcinoma as secondary or adjuvant treatment when the following indications are met¹³⁸:
 - Carcinoma in situ at margin; **OR**
 - Positive regional nodes; **OR**
 - Resected gross residual disease ([R2](#)); **OR**
 - Resected, positive margin ([R1](#)); **OR**
- Esophageal cancer when the following indications are met^{18,125}:
 - Palliative treatment for dysphagia; **OR**
 - Unresectable, nonmetastatic disease; **OR**
- Gynecologic cancer (cervical, endometrial/uterine, vaginal or vulvar); **OR**
- Head and neck cancer (brain, lip, nasopharyngeal, oral cavity, salivary gland, uveal melanoma); **OR**
- Intracoronary application for in-stent restenosis following angioplasty or stent placement¹⁰; **OR**
- Lung cancer when the following indications are met^{12,26,97}:
 - Endobronchial treatment of the central airway in an individual who are not candidates for surgical resection; **OR**
 - Palliative treatment for an individual with unresectable disease and symptomatic airway obstruction; **OR**
- Neuroendocrine tumors when the following indications are met⁹⁶:
 - Metastasis to the liver when systemic therapy is contraindicated; **OR**
 - Systemic therapy has failed to control symptoms (eg, carcinoid syndrome); **OR**
- Penile cancer when the following indications are met⁹⁸:

- Node negative; **AND**
- [T1](#) or [T2](#) disease; **AND**
- Tumors less than 4 cm confined to the glans and prepuce; **OR**
- Prostate cancer when the following requirements are met:
 - Low risk localized prostate cancer when the following indications are met^{36,82}:
 - Grade group 1 (Gleason score less than 6); **AND**
 - Serum PSA less than 10 ng/ml; **AND**
 - Stage [T1](#) or [T2a](#); **OR**
 - Intermediate-risk prostate cancer when the following indications are met^{36,82}:
 - Grade group 2-3 (Gleason score 7); **AND**
 - Serum PSA greater than or equal to 10 ng/ml and less than 20 ng/ml; **AND**
 - Stage [T2b – T2c](#); **OR**
 - High-risk prostate cancer as a boost when the following indications are met^{36,82}:
 - Grade group 4-5 (Gleason score 8-10); **AND**
 - Serum PSA greater than or equal to 20 ng/ml; **AND**
 - Stage [T3](#) or greater⁶⁰; **OR**
- Retinoblastoma when the following indications are met^{6,64}:
 - As a secondary treatment after local treatment failure (eg, cryoablation, external beam radiation therapy [EBRT], laser therapy, local or systemic chemotherapy); **OR**
- SIRT when the following indications are met:
 - SIR-Spheres for unresectable metastatic liver tumors from primary colorectal cancer (CRC) with adjuvant intra-hepatic artery chemotherapy¹⁴⁵; **OR**
 - TheraSphere when the following indications are met¹⁴⁶:
 - Unresectable HCC of solitary tumor (1-8 cm in diameter); **AND**
 - [Child-Turcotte-Pugh Score A](#) cirrhosis; **AND**
 - [Eastern Cooperative Oncology Group \(ECOG\) Performance status of 0-2](#); **AND**
 - No macrovascular invasion; **AND**

- Well-compensated liver function (eg, no signs or symptoms of decompensation such as ascites, hepatic encephalopathy, jaundice or variceal hemorrhage)
- Soft tissue sarcoma when the following indications are met^{64,101}:
 - Positive margins; **AND**
 - Tumor size greater than 5 cm

Electronic brachytherapy will be considered medically reasonable and necessary with documentation of medical necessity for the following³⁸:

- Interstitial applications
- Intracavity applications
- Skin surface applications

Transperineal biodegradable spacer also known as **prostate rectal spacers** (eg, Barrigel, SpaceOar, SpaceOAR Vue) will be considered medically reasonable and necessary for use during prostate cancer radiation therapy.

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

[US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage](#)

The following services will not be considered medically reasonable and necessary:

- Age-related macular degeneration
- Intravascular brachytherapy following femoropopliteal angioplasty
- Noninvasive brachytherapy
- Pancreatic cancer

A review of the current medical literature shows that there is no evidence to determine that these services are standard medical treatments. There is an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

The following service will not be considered medically reasonable and necessary:

- Bladder cancer

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

Summary of Evidence

Bladder Cancer

Interstitial brachytherapy has been used in a number of specialized centers to treat small, solitary muscle-invasive bladder cancers; however, the quality of this evidence is low and the role of selection is paramount. It has not been determined whether interstitial brachytherapy reduces local recurrence rates.³⁷

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
19296	Placement of radiotherapy afterloading expandable catheter (single or multichannel) into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy	
19297	Placement of radiotherapy afterloading expandable catheter (single or multichannel) into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy (List separately in addition to code for primary procedure)	
19298	Placement of radiotherapy after loading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance	
19499	Unlisted procedure, breast	

20555	Placement of needles or catheters into muscle and/or soft tissue for subsequent interstitial radioelement application (at the time of or subsequent to the procedure)	
31643	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of catheter(s) for intracavitary radioelement application	
41019	Placement of needles, catheters, or other device(s) into the head and/or neck region (percutaneous, transoral, or transnasal) for subsequent interstitial radioelement application	
55860	Exposure of prostate, any approach, for insertion of radioactive substance;	
55862	Exposure of prostate, any approach, for insertion of radioactive substance; with lymph node biopsy(s) (limited pelvic lymphadenectomy)	
55865	Exposure of prostate, any approach, for insertion of radioactive substance; with bilateral pelvic lymphadenectomy, including external iliac, hypogastric and obturator nodes	
55874	Transperineal placement of biodegradable material, periprostatic, single or multiple injection(s), including image guidance, when performed	
55875	Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy	
55876	Placement of interstitial device(s) for radiation therapy guidance (eg, fiducial markers, dosimeter), prostate (via needle, any approach), single or multiple	
55920	Placement of needles or catheters into pelvic organs and/or genitalia (except prostate) for subsequent interstitial radioelement application	
57155	Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy	
57156	Insertion of a vaginal radiation afterloading apparatus for clinical brachytherapy	
58346	Insertion of Heyman capsules for clinical brachytherapy	
61770	Stereotactic localization, including burr hole(s), with insertion of catheter(s) or probe(s) for placement of radiation source	
76873	Ultrasound, transrectal; prostate volume study for brachytherapy treatment planning (separate procedure)	
76965	Ultrasonic guidance for interstitial radioelement application	

77316	Brachytherapy isodose plan; simple (calculation[s] made from 1 to 4 sources, or remote afterloading brachytherapy, 1 channel), includes basic dosimetry calculation(s)	
77317	Brachytherapy isodose plan; intermediate (calculation[s] made from 5 to 10 sources, or remote afterloading brachytherapy, 2-12 channels), includes basic dosimetry calculation(s)	
77318	Brachytherapy isodose plan; complex (calculation[s] made from over 10 sources, or remote afterloading brachytherapy, over 12 channels), includes basic dosimetry calculation(s)	
77424	Intraoperative radiation treatment delivery, x-ray, single treatment session	
77425	Intraoperative radiation treatment delivery, electrons, single treatment session	
77750	Infusion or instillation of radioelement solution (includes 3-month follow-up care)	
77761	Intracavitary radiation source application; simple	
77762	Intracavitary radiation source application; intermediate	
77763	Intracavitary radiation source application; complex	
77767	Remote afterloading high dose rate radionuclide skin surface brachytherapy, includes basic dosimetry, when performed; lesion diameter up to 2.0 cm or 1 channel	
77768	Remote afterloading high dose rate radionuclide skin surface brachytherapy, includes basic dosimetry, when performed; lesion diameter over 2.0 cm and 2 or more channels, or multiple lesions	
77770	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 1 channel	
77771	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 2-12 channels	
77772	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; over 12 channels	
77778	Interstitial radiation source application, complex, includes supervision, handling, loading of radiation source, when performed	
77789	Surface application of low dose rate radionuclide source	
77790	Supervision, handling, loading of radiation source	
77799	Unlisted procedure, clinical brachytherapy	

92974	Transcatheter placement of radiation delivery device for subsequent coronary intravascular brachytherapy (List separately in addition to code for primary procedure)	
CPT® Category III Code(s)	Description	Comments
0394T	High dose rate electronic brachytherapy, skin surface application, per fraction, includes basic dosimetry, when performed	
0395T	High dose rate electronic brachytherapy, interstitial or intracavitary treatment, per fraction, includes basic dosimetry, when performed	
0735T	Preparation of tumor cavity, with placement of a radiation therapy applicator for intraoperative radiation therapy (IORT) concurrent with primary craniotomy (List separately in addition to code for primary procedure)	
HCPCS Code(s)	Description	Comments
A9527	Iodine I-125, sodium iodide solution, therapeutic, per mCi	
C1715	Brachytherapy needle	
C1716	Brachytherapy source, nonstranded, gold-198, per source	
C1717	Brachytherapy source, nonstranded, high dose rate iridium-192, per source	
C1719	Brachytherapy source, nonstranded, nonhigh dose rate iridium-192, per source	
C1728	Catheter, brachytherapy seed administration	
C2616	Brachytherapy source, nonstranded, yttrium-90, per source	
C2634	Brachytherapy source, nonstranded, high activity, iodine-125, greater than 1.01 mCi (NIST), per source	
C2635	Brachytherapy source, nonstranded, high activity, palladium-103, greater than 2.2 mCi (NIST), per source	
C2636	Brachytherapy linear source, nonstranded, palladium-103, per 1 mm	
C2637	Brachytherapy source, nonstranded, ytterbium-169, per source	
C2638	Brachytherapy source, stranded, iodine-125, per source	
C2639	Brachytherapy source, nonstranded, iodine-125, per source	
C2640	Brachytherapy source, stranded, palladium-103, per source	
C2641	Brachytherapy source, nonstranded, palladium-103, per source	
C2642	Brachytherapy source, stranded, cesium-131, per source	
C2643	Brachytherapy source, nonstranded, cesium-131, per source	
C2644	Brachytherapy source, cesium-131 chloride solution, per mCi	

C2645	Brachytherapy planar source, palladium-103, per sq mm	
C2698	Brachytherapy source, stranded, not otherwise specified, per source	
C2699	Brachytherapy source, nonstranded, not otherwise specified, per source	
C7533	Percutaneous transluminal coronary angioplasty, single major coronary artery or branch with transcatheter placement of radiation delivery device for subsequent coronary intravascular brachytherapy	
C9725	Placement of endorectal intracavitary applicator for high intensity brachytherapy	
C9726	Placement and removal (if performed) of applicator into breast for intraoperative radiation therapy, add-on to primary breast procedure	
C9728	Placement of interstitial device(s) for radiation therapy/surgery guidance (e.g., fiducial markers, dosimeter), for other than the following sites (any approach): abdomen, pelvis, prostate, retroperitoneum, thorax, single or multiple	
G0458	Low dose rate (LDR) prostate brachytherapy services, composite rate	
Q3001	Radioelements for brachytherapy, any type, each	

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Appendix

Appendix A – Residual tumor (R) classification¹⁷⁹

Rx	The presence of residual tumor cannot be assessed
R0	No residual tumor
R1	Microscopic residual tumor
R2	Macroscopic residual tumor

Appendix B – TNM Staging System for Prostate Cancer¹³¹

Primary tumor (T)	
Clinical T (cT)	
T category	T criteria
TX	Primary tumor cannot be assessed
T0	No evidence of primary tumor
T1	Clinically inapparent tumor that is not palpable
T1a	Tumor incidental histologic finding in 5% or less of tissue resected
T1b	Tumor incidental histologic finding in more than 5% of tissue resected
T1c	Tumor identified by needle biopsy found in one or both sides, but not palpable
T2	Tumor is palpable and confined within prostate
T2a	Tumor involves one-half of one side or less
T2b	Tumor involves more than one-half of one side but not both sides
T2c	Tumor involves both sides
T3	Extraprostatic tumor that is not fixed or does not invade adjacent structures
T3a	Extraprostatic extension (unilateral or bilateral)
T3b	Tumor invades seminal vesicle(s)

T4	Tumor is fixed or invades adjacent structures other than seminal vesicles such as external sphincter, rectum, bladder, levator muscles, and/or pelvic wall
Pathological T (pT)	
T category	T criteria
T2	Organ confined
T3	Extraprostatic extension
T3a	Extraprostatic extension (unilateral or bilateral) or microscopic invasion of bladder neck
T3b	Tumor invades seminal vesicle(s)
T4	Tumor is fixed or invades adjacent structures other than seminal vesicles such as external sphincter, rectum, bladder, levator muscles, and/or pelvic wall
<p>Note: There is no pathological T1 classification.</p> <p>Note: Positive surgical margin should be indicated by an R1 descriptor, indicating residual microscopic disease.</p>	

Appendix C – Child-Turcotte-Pugh Classification⁷⁰

CTP classification: Child A: score of 5-6; Child B: score of 7-9; Child C: score of 10-15

Parameters	Points Ascribed		
	1	2	3
Ascites	None	Grade 1-2 (or easy to treat)	Grade 3-4 (or refractory)
Hepatic Encephalopathy	None	Grade 1-2 (or induced by a precipitant)	Grade 3-4 (or spontaneous)
Bilirubin (mg/dL)	Less than 2	2-3	Greater than 3
Albumin (g/dL)	Greater than 3.5	2.8-3.5	Less than 2.8
Prothrombin time (seconds greater than control) or INR	Less than 4 Less than 1.7	4-6 1.7-2.3	Greater than 6 Greater than 2.3

Appendix D – Tumor staging for penile cancer (TNM staging)¹³⁰

T category	T criteria
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TX	Primary tumor cannot be assessed
T0	No evidence of primary tumor
Tis	Carcinoma <i>in situ</i> (penile intraepithelial neoplasia [PeIN])
Ta	Noninvasive localized squamous cell carcinoma
T1	Glans: Tumor invades lamina propria. Foreskin: Tumor invades dermis, lamina propria, or dartos fascia. Shaft: Tumor invades connective tissue between epidermis and corpora regardless of location. All sites with or without lymphovascular invasion or perineural invasion and is or is not high grade.
T1a	Tumor is without lymphovascular invasion or perineural invasion and is not high grade (ie, grade 3 or sarcomatoid)
T1b	Tumor exhibits lymphovascular invasion and/or perineural invasion or is high grade (ie, grade 3 or sarcomatoid)
T2	Tumor invades into corpus spongiosum (either glans or ventral shaft) with or without urethral invasion
T3	Tumor invades into corpora cavernosum (including tunica albuginea) with or without urethral invasion
T4	Tumor invades into adjacent structures (ie, scrotum, prostate, pubic bone)

Appendix E – Eastern Cooperative Oncology Group (ECOG) performance status⁷⁰

Performance status	Definition
0	Fully active; no performance restrictions.
1	Strenuous physical activity restricted; fully ambulatory and able to carry out light work.
2	Capable of all self-care but unable to carry out any work activities. Up and about >50% of waking hours.
3	Capable of only limited self-care; confined to bed or chair >50% of waking hours.

4

Completely disabled; cannot carry out any self-care; totally confined to bed or chair.

Change Summary

- Click or tap to enter a date. **New Policy.**

-