

Medicare Advantage Medical Policy



Nonprofit corporations and independent licensees
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Radiostereometric Analysis (RSA) – Medicare Advantage

Medicare Advantage Plan

- ☒ Medicare Plus BlueSM
- ☒ BCN AdvantageSM

UM Committee Approval Date: 03/19/2025

Effective Date: 04/19/2025

Description

Radiostereometric analysis (RSA), is an imaging technique in which highly accurate 3-dimensional measurements *in vivo* through the analysis of sequential radiographs. By utilizing a dual X-ray imaging system, RSA allows for the simultaneous capture of two X-ray images from different angles, providing a stereoscopic view of the subject. This technique is primarily used to assess the stability and migration of joint replacement implants, such as those in the knee, hip, shoulder, and spine, by quantifying their movement relative to the surrounding bone over time. By comparing the implant's position to its original location, RSA is proposed to provide insights into the implant's performance and stability.

Related Medical Coverage Policies

- N/A

Policy Guidelines

Blue Cross Blue Shield of Michigan (BCBSM) and Blue Care Network of Michigan (BCN) adhere to guidance from the Centers for Medicare and Medicaid Services (CMS), including when performing organization determinations for Medicare Advantage plan members. CMS Medicare statutes, regulations, manuals, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and other sub-regulatory guidance provide the clinical guidelines for coverage determinations, payment integrity functions, and all other uses by CMS regulations. When CMS Medicare guidance is not fully established, CMS permits BCBSM/BCN to utilize "internal coverage criteria", such as independent criteria, health plan policy research, LCD/LCAs outside the services area or research from independent medical research repositories (i.e., Hayes) for coverage policies 42 CFR § 422.101. BCBSM/BCN internal medical coverage policies are developed and based on current evidence in widely accepted treatment guidelines or clinical literature; in addition, they address how clinical benefits may or may not outweigh member harm.

The following is applicable for this medical policy:

After searching the Medicare Coverage Database and other sources of conditions of coverage, it was determined that CMS guidance is not fully developed, related to codes found in this medical policy. BCBSM/BCN internal policy coverage criteria will be applied where CMS guidance is absent.

Code	Description	NCD/LCD/LCA	Additional Guidance
0347T	Placement of interstitial device(s) in bone for radiostereometric analysis (RSA).	National Coverage Determinations None	When the NCD or LCDs/LCAs do not have fully established clinical coverage criteria to determine medical necessity for radiostereometric analysis (RSA) refer to the BCBSM/BCN policy: <i>Radiostereometric Analysis (RSA)</i> Policy attached below.
0348T	Radiologic examination, radiostereometric analysis (RSA); spine.	Local Coverage Determinations/Articles None	
0349T	Radiologic examination, radiostereometric analysis (RSA); upper extremity(ies).		
0350T	Radiologic examination, radiostereometric analysis (RSA); lower extremity(ies).		

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HCPCS® codes, descriptions and materials are copyrighted by Centers for Medicare and Medicaid Services (CMS).

The above information is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. Please refer to the Medicare Coverage Database website at <https://www.cms.gov/medicare-coverage-database/search.aspx> for the most current applicable NCD, LCD, LCA, and CMS Online Manual System Transmittals.

CMS Medicare Administrative Contractors (MAC) Jurisdictions

Part A and Part B Medicare Administrative Contractor (MAC) Jurisdiction	
Wisconsin Physicians Service Insurance Corporation (WPS)	IA, IN, KS, MI, MO, NE
CGS Administrators, LLC	KY, OH
First Coast Service Options, Inc	FL, PR, US VI
National Government Services, Inc (NGS)	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI,
Noridian Healthcare Solutions, LLC, Jurisdiction JE	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands
Noridian Healthcare Solutions, LLC, Jurisdiction JF	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
Novitas Solutions, Inc	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX,
Palmetto GBA	AL, GA, TN NC, SC, VA, WV
DME MAC Jurisdictions	
CGS Administrators, LLC, Jurisdictions JB and JC	AL, AR, CO, FL, GA, IL, IN, KY, LA, MI, MN, MS, NM, NC, OH, OK, Puerto Rico, SC, TN, TX, VA, Virgin Island, WI, WV
Noridian Healthcare Solutions, LLC, Jurisdictions JA and JD	AK, American Soamoa, AZ, CA, CT, DE, DC, Guam, HI, ID, IA, KS, MA, MD, ME, MO, MT, ND, NE, NH, NJ, NV, NY, Northern Mariana Islands, OR, PA, RI, SD, UT, VT, WA, WY

Important Reminder

BCBSM and BCN follow CMS Medicare coverage guidance to limit coverage to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member. Medicare Advantage Medical Policies list the criteria BCBSM and BCN use to decide which medical services are considered “reasonable and necessary” when Medicare coverage rules are not fully developed, or as otherwise may be permitted by CMS Medicare regulations. Individual member benefit plan documents, such as the Evidence of Coverage and Annual Notice of Change, as well as applicable laws govern benefit coverage, including any inclusion, exclusion, and/or other restrictions.

Medicare Advantage Medical policies are created when permitted by CMS Medicare regulations, reviewed regularly, and may be revised periodically. BCBSM/BCN Medical Policies are proprietary and should not be copied or disseminated without the express, prior written approval of BCBSM. All providers are required to review applicable BCBSM reimbursement policies prior to claim submission and bill for covered services in accordance with those policies. Additionally, providers contracted with BCBSM or BCN’s Medicare Advantage network(s) should review the provider manual for any additional claim submission requirements. Providers not contracted with BCBSM or BCN’s Medicare Advantage network may be required to submit documentation to BCBSM, BCN, or its delegated entity supporting billed claims, including but not limited to applicable medical records.

Note: U.S. Food and Drug Administration (FDA) approval for a specific indication or the issuance of a CPT code is not sufficient for a procedure to be considered medically reasonable and necessary. Similarly, the presence of a procedure/device code or payment amount for the service in the Medicare fee schedule does not necessarily indicate coverage. If a service is deemed not reasonable and necessary, to treat illness or injury for any reason (including lack of safety and efficacy because it is an experimental procedure, etc.), the procedure is considered not covered.

Disclaimer: This medical policy is not an authorization, certification, explanation of benefits, or a contract for the services, devices, or drugs that is referenced in the medical policy. Medical policies do not constitute medical advice and do not guarantee any results or outcomes or guarantee payment. The medical policy is not intended to replace independent medical judgment for treatment of individuals. Treating physicians and health care providers are solely responsible for determining what care to provide to their patients. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another.

Pursuant to Section 1557 and Section 504, Blue Cross does not discriminate on the basis of race, color, national origin, age, disability, or sex (including sex characteristics, intersex traits; pregnancy or related conditions; sexual orientation; gender identity, and sex stereotypes). This includes our rules, benefit designs and medical policies.

BCBSM/BCN Medicare Advantage Policy History

Policy Effective Date	UM Committee Approval Date	Comments
07/17/2024	07/17/2024	Medicare Advantage policy established
04/19/2025	03/19/2025	MA policy foundational language updated. Adoption of JUMP policy updates.

Medical Policy



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Joint Medical Policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and is therefore subject to change.

***Current Policy Effective Date: 3/1/25**
(See policy history boxes for previous effective dates)

Title: Radiostereometric Analysis (RSA)

Description/Background

Radiostereometric analysis (RSA), also called Roentgen stereophotogrammetry, is an imaging technique in which highly accurate 3-dimensional measurements *in vivo* are calculated via sequential radiographs. Two x-ray imaging systems are integrated via a stationary digital platform through a synchronization switch. The switch allows the 2 x-ray imaging systems to fire simultaneously, providing a pair of x-ray images from different perspectives to be taken at the exact same time.

For individuals who have undergone artificial joint replacement surgery, implant loosening and migration are common reasons for failure. RSA is performed largely to assess joint replacements in order to quantify the migration of the implant compared to its original location relative to the bone. RSA has been used to evaluate implants primarily involving the knee, hip, shoulder, and spine.

During surgery, the surgeon implants multiple poppy seed size titanium marker beads into the bone surrounding the implant. The beads integrate into the bone and are used as references to determine any future joint implant migration changes that may occur. Post-operatively, RSA creates a stereo image of the joint by taking 2 x-rays from different directions at the same time. An interactive software system analyzes the 2 radiographs and the 3-dimensional position of each *in vivo* marker, allowing surgeons to precisely measure within 2/10's of a millimeter. Displacements between the 2 segments are calculated and evaluated for implant migration.

RSA has been used mostly for research purposes. While the data obtained holds value for future cases, as it can provide pertinent information regarding design improvement and long-term stability of a particular implant, the clinical utility of RSA is uncertain with regard to pre-surgical planning or as a means to guide current management. Gathering this information results in the current individual enduring added risks including extended surgery times, longer

anesthesia exposure, potential for migration of marker beads, infection, bleeding, blood clots, and increased radiation exposure and lacks the benefit of improved care or clinical outcomes.

Regulatory Status

In 2009, Halifax Biomedical, Inc. received FDA 510(k) marketing clearance for tantalum bead implants for use as radio-opaque markers and for implantation into bone or soft tissue. These devices are used to measure movement of implants after surgery with the aid of an x-ray system. Implant surgery associated with the use of radiographic markers may include total joint replacement procedures, soft tissue repair and bone fracture fixation procedures.

Additionally, Halifax Biomedical received 510(k) marketing clearance in 2012 for the SR Suite 1.0, which is a stationary digital x-ray system for general radiography and RSA (Roentgen Stereophotogrammetric Analysis procedures). A software imaging analysis system, the RSA-CMS (Medis Medical Imaging Systems) received 510(k) marketing clearance in 2004.

In 2018, Halifax Biomedical received 510(k) marketing clearance for the Halifax Imaging Kit. The Halifax Imaging Kit is part of the SR Suite product line and provides an alternative path to creating an SR Suite. The Halifax Imaging Kit consists of FDA cleared and/or certified x-ray components integrated into an existing digital radiography room already containing an FDA cleared x-ray imaging system to form an SR Suite. The exposures of the Halifax Imaging Kit and the existing Digital Radiography (DR) system are synchronized by replacing the trigger switches of the two systems with either the Universal Synchronization Switch or the Imaging Kit Control Module.

Per labeling, the device is not meant for mammography.

Product code: LLZ

Medical Policy Statement

Radiostereometric analysis (RSA) is experimental/investigational. It has not been scientifically demonstrated to improve clinical outcomes.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

0347T

0348T

0349T

0350T

Rationale

There are numerous publications that describe the value of RSA in an experimental setting with regard to evaluating implant migration in the post-surgical period. RSA has the ability to identify implant migration long before clinical failure will be evident and is therefore considered to be a valuable method for evaluating new implant designs. However, evidence is lacking as to the utility of RSA outside the research setting. While RSA can be considered as a screening tool for novel orthopedic implants, its role in clinical practice is uncertain.

Valstar et al (2005) published RSA standardization guidelines, which are likely to play a critical role in enabling the comparison of RSA studies. Although RSA is a powerful device in the clinical research arena, it is currently unproven for clinical practice. RSA requires the implantation of bone markers, as well as investment in the technology and personnel. Furthermore, the RSA technique is very time consuming and labor intensive. Until it is established that RSA can directly impact care and medical decision making, RSA will be considered experimental.

Large randomized controlled trials comparing RSA to other imaging techniques are needed to determine whether this technology is more effective and improves health outcomes over conventional methods.

Government Regulations

National:

There is no national coverage determination on this topic.

Local:

There is no local coverage determination on this topic.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

References

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2. Biedermann, R. et al, "Evaluation of accuracy and precision of bone markers for the measurement of migration of hip prostheses: A Comparison of Conventional Measurements," *J Bone Joint Surg [Br]* 2001;83-B:767-71.
3. Bottner, F. et al, "Radiostereometric Analysis: The Hip," *HSSJ* (2005) 1:94–99.
4. Bragdon, CR et al, "Radiostereometric Analysis (RSA) Studies at Massachusetts General Hospital," http://www.orthojournalhms.org/volume10/manuscripts/PDF/V10_66.pdf. Accessed October 4, 2024.
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10. Schepull, T. et al, "Mechanical properties during healing of Achilles tendon ruptures to predict final outcome: A pilot Roentgen stereophotogrammetric analysis in 10 patients," *BMC Musculoskeletal Disorders* 2007, 8:116.
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13. Solomon, Lucian and Stuart A. Callary, "Emerging Ideas Soft Tissue Applications of Radiostereometric Analysis," *Clin Orthop Relat Res* (2011) 469:1512–1516.
14. Stilling, M et al, "Precision of novel radiological methods in relation to resurfacing humeral head implants: assessment by radiostereometric analysis, DXA, and geometrical analysis" *Arch Orthop Trauma Surg* (2012) 132: 1521 – 1530.
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16. Valstar, ER et al, "Guidelines for standardization of radiostereometry (RSA) of implants," *Acta Orthopaedica* 2005; 76 (4): 563–572.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through October 4, 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
1/1/15	10/21/14	11/7/14	Joint policy established
1/1/16	10/13/15	10/27/15	Routine maintenance
1/1/17	10/11/16	10/11/16	Routine maintenance
1/1/18	10/19/17	10/19/17	Routine maintenance
1/1/19	10/16/18	10/16/18	Routine maintenance
1/1/20	10/15/19		Routine maintenance
3/1/20	12/17/19		Routine maintenance
3/1/21	12/15/20		Routine maintenance
3/1/22	12/14/21		Routine maintenance
3/1/23	12/20/22		Routine maintenance (slp)
3/1/24	12/19/23		Routine maintenance (slp) Vendor managed: N/A
3/1/25	12/17/24		Routine maintenance (slp) Vendor managed: N/A

Next Review Date: 4th Qtr, 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: RADIOSTEREOMETRIC ANALYSIS (RSA)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.