Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***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 trails 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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11. Sesselmann, S et al, “Radiostereometric analysis of hip implants: a critical review of methodology and future directions,” *OA Musculoskeletal Medicine* 2013 Dec 01;1(4):31.
12. Sköldenberg, O. et al, “Measurement of the migration of a focal knee resurfacing implant with radiostereometry: An experimental study,” *Acta Orthopaedica* 2014; 85 (1): 79–83.
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.
15. U.S. Food and Drug Administration. Halifax Biomeidcal – Halifax Imaging Kit. 501(k) approval. 2018. https://www.accessdata.fda.gov/cdrh_docs/pdf18/K182880.pdf. Accessed October 4, 2024.
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.