
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: 1/1/25**
(See policy history boxes for previous effective dates)

Title: Magnetic Resonance Imaging - Low Field

Description/Background

Low-field magnetic resonance imaging (MRI) is generally considered to include scanners with a magnetic field strength of 0.5 Tesla (T) or less. Intermediate-field MRI generally includes scanners of greater than 0.5T and less than 1.5T, and high-field MRI includes scanners of 1.5T or greater. Most imaging facilities offer conventional MRI using scanners with a 1.5T magnet, and 3T scanners are widely available. Advantages of high-field MRI include improved signal-to-noise ratio, improved contrast-to-noise ratio, and improved spatial and temporal resolution compared to lower-field scanners. Advantages of lower-field MRI include easier installation, due to the smaller machine; lower cost; and a variety of configurations to maximize patient comfort.¹ There is also a reduced safety risk to the patient and reduction of artifacts that are associated with higher field strengths.

Open MRI refers to a scanner in which the magnets are located above and below the patient, rather than in a cylindrical bore as is the case with conventional MRI scanners. The majority of open MRI scanners are 0.2 to 0.3T. Advantages to open MRI include the ability to image patients who are unable to tolerate conventional MRI due to claustrophobia, as well as larger-sized patients. Positional MRI involves obtaining MRI images with the patient in a position other than supine; primarily, this refers to images obtained with the patient seated or standing upright. Often, these studies require the use of an open MRI scanner of low field strength.¹

Regulatory Status:

In 2020, the U.S. Food and Drug Administration approved 510(k) clearance for the Hyperfine (Guilford, CT) Swoop™ portable MR scanner (K211818).²

In 2021, the FDA approved 510(k) clearance for Siemens (Germany) Healthineers Magnetom Free.Max (K210611).³

Product code LNH, MOS.

In 2021, the FDA approved 510(k) clearance for Hyperfine's deep-learning image analysis software, an artificial intelligence application for the Swoop.⁴

Medical Policy Statement

Low-field magnetic resonance imaging is considered established in specific clinical situations.

Inclusionary and Exclusionary Guidelines

Low-field magnetic resonance imaging may be considered established when:

- the patient meets criteria for a magnetic resonance imaging test; and
 - the health care provider determines low-field MRI is clinically appropriate.
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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:

S8042

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

NA

Rationale

Contraindications to intermediate- or high-field MRI for which low-field MRI is possible include claustrophobia and patient size. A standard MRI has a bore opening of 60 cm, and some wide-bore MRI units have an opening of 80 cm diameter. For patients in whom the bore size is a limiting factor, open MRI may be appropriate.¹

In addition to use when intermediate- or high-field MRI is contraindicated, low-field MRI is being investigated as an alternative to standard MRI.

Government Regulations

National:

National Coverage Determination (NCD): Magnetic Resonance Imaging 220.2

Medicare does not differentiate between low-field magnetic resonance imaging and conventional imaging.

Medicare does not reimburse for “S” codes.

Local:

NA

(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

- Magnetic Resonance Angiography and Venography (retired)
 - Magnetic Resonance Angiography of the Spine (retired)
 - Magnetic Resonance Cholangiopancreatography (retired)
 - Magnetic Resonance Imaging (retired)
 - Magnetic Resonance Imaging for Detection and Diagnosis of Breast Cancer
 - Magnetic Resonance Imaging to Monitor Integrity of Silicone-Gel-Filled Breast Implants
 - Magnetic Resonance-Guided Focused Ultrasound (MRgFUS)
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References

1. AIM Clinical Appropriateness Guidelines, Advanced Imaging. Appropriate Use Criteria: Low-field MRI. Effective January 1, 2021.
2. U.S. Food and Drug Administration. 510(k) premarket notification. Hyperfine Swoop. https://www.accessdata.fda.gov/cdrh_docs/pdf21/K211818.pdf Accessed 8/22/24.
3. U.S. Food and Drug Administration. 510(k) premarket notification. Magnetom Free.Max. https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210611.pdf Accessed 8/22/24.
4. U.S Food and Drug Administration 510K(k) Premarket Notification Swoop Portable MR Imaging System [510\(k\) Premarket Notification \(fda.gov\) 510\(k\) Premarket Notification \(fda.gov\)](https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210611.pdf) Accessed 8/22/24
5. Centers for Medicare and Medicaid. National Coverage Determination (NCD) for Magnetic Resonance Imaging (220.2). Effective date 7/7/11, Revision effective date 4/10/18. <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=177&ncdver=5&SearchType=Advanced&CoverageSelection=Both&NCSselection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD%7cED&PolicyType=Both&s=27&Keyword=magnetic+resonance+imaging&KeywordLookUp=Title&KeywordSearchType=Exact&kq=true&bc=IAAACAAAAAAA%3d%3d&> Accessed 8/22/24.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 8/22/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

| Policy Effective Date | BCBSM Signature Date | BCN Signature Date | Comments |
|------------------------------|-----------------------------|---------------------------|---|
| 3/1/07 | 1/10/07 | 12/22/06 | Joint policy established |
| 3/1/08 | 12/11/07 | 3/1/08 | Routine maintenance |
| 3/1/09 | 12/9/08 | 12/21/08 | Routine maintenance |
| 7/1/10 | 4/20/10 | 4/20/10 | Routine maintenance |
| 3/1/13 | 12/10/13 | 1/6/14 | Routine maintenance |
| 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 |
| 1/1/21 | 10/20/20 | | Routine maintenance Ref 15 added |
| 1/1/22 | 10/19/21 | | New-Existing policy review. Position change to established. Ref 1,2,3 added. |
| 1/1/23 | 10/18/22 | | Routine maintenance (ls) |
| 1/1/24 | 10/17/23 | | Routine maintenance (jf) Vendor Managed: NA |
| 1/1/25 | 10/15/24 | | Routine maintenance (jf) Vendor Managed: NA |

Next Review Date: 4th Qtr, 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: MAGNETIC RESONANCE IMAGING - LOW FIELD

I. Coverage Determination:

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| Commercial HMO (includes Self-Funded groups unless otherwise specified) | Not covered |
| BCNA (Medicare Advantage) | See Government Regulations section. Medicare does not reimburse S codes. |
| 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.