Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 7/1/23**
(See policy history boxes for previous effective dates)

Title: Powered Bone Marrow Aspiration and Biopsy Systems

Description/Background

Bone marrow aspiration and biopsy are procedures to obtain the blood-producing portion of the inner core of bone (the marrow) to evaluate blood cell production and to help diagnose certain illnesses, such as leukemia. They are also performed to diagnose and stage other types of cancer that may have spread into the marrow, and to help determine the cause of severe anemia.

Bone marrow is obtained by inserting a special needle into a bone that contains the red spongy marrow, usually the posterior superior iliac crest. A small sample of the marrow is withdrawn, either via suction or by coring out a section. The standard method of collecting bone marrow involves making a tiny incision in the skin through which a T-shaped device containing a special needle is inserted. Once the needle device reaches the bone, it is slowly advanced by manually rotating clockwise and counterclockwise until the bone is penetrated, and the marrow cavity is entered. Approximately 0.3 ml of bone marrow is aspirated via a syringe. Once the sample is obtained, the needle is removed, and pressure is applied to the site until any bleeding has stopped.

Over the past several years, battery-powered bone marrow aspiration and biopsy systems have been developed. When compared to the traditional method of manually collecting bone marrow, it is reported that these powered devices offer larger specimen samples, decreased procedure time and significantly less pain for the patient.

One such device, the Oncontrol™ Bone Marrow System manufactured by Vidacare, uses a lithium battery-powered hand-held drill with a special needle attachment that drills through the hard bone cortex. Once the needle has reached the bone, the inner stylet of the needle is removed, and a syringe is attached to collect bone marrow aspirate. Similarly, for a bone marrow biopsy, the bone is accessed via the battery-powered drill and a special needle cannula

is employed to “grab” a portion of bone marrow for sampling. Once the marrow is obtained, the needle is removed, and the marrow sample is stored in a special collection kit.

Regulatory Status:

The U.S. Food and Drug Administration (FDA; 2007) granted 510(k) clearance for a powered bone marrow biopsy system, OnControl by Vidacare Corporation, for obtaining samples for diagnostic examination. Examples of similar devices approved by the FDA include the EZ-IO® Bone Marrow Aspiration System by Vidacare, the Bone Marrow Harvest System by BioAccess and the InterV TrapLok™ Bone Marrow Biopsy Needle by Medical Devices Technologies. Product codes: KNW, FMI

Medical Policy Statement

The clinical utility of powered bone marrow aspiration and biopsy systems has not been scientifically demonstrated. These devices have not been shown to improve long term clinical outcomes better than standard methods. Therefore, this service is experimental/ investigational.

Inclusionary and Exclusionary Guidelines

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.):

C1830

Rationale

Forwood et al (2019) compared bone marrow trephine sample quality between OnControl drill system and the Jamshidi needle. There were 164 samples assessed (Jamshidi n = 69, OnControl, same site as aspirate n = 48, OnControl, separate site from aspirate n = 47). The assessable and total length were similar between the Jamshidi and OnControl techniques, with increased crush artefact observed with the OnControl drill ($p < 0.001$). Using a separate puncture site for trephine collection and aspirate did not reduce the artefact seen with the OnControl system ($p = 0.274$). Smaller samples ($p < 0.001$) and an increase in crushed ($p = 0.009$) and connective tissue ($P = 0.002$) were seen in trephines obtained by

nonlaboratory-based trainees, regardless of the needle used or their stage of training, compared to laboratory trainees. The OnControl system was associated with more artefact, a finding in line with previous studies. There was no improvement by sampling the trephine from a separate site to the aspirate. Laboratory-based trainees who reviewed marrow morphology produced trephines with better assessable length than those not based in the laboratory.

Jain et al (2017) completed a retrospective analysis to compare the adequacy and quality of bone marrow obtained by a powered drill (P-group) versus via manual procedure (M-group). Seventy-five bone marrow specimens were obtained. Forty-four were obtained manually and thirty-one were obtained with the OnControl battery powered system. Comparisons included biopsy length, evaluable marrow length and total area, fragmentation, aspiration and marrow dropout artefacts. Biopsies were sufficient for diagnosis in 38/44 cases (86%) in the M-group and in 26/31 cases (83%) in the P-group. The most common reason for suboptimal/inadequate biopsies was subcortical specimens (4/6) in the M-group and aspiration artefact (5/5) in the P-group. Average length after fixation, evaluable marrow length, and evaluable marrow area were comparable. Aspiration artefact was minimal (<10%) in the majority of BM samples in the M-group (31/44), while 25/31 BM in the P-group showed >10% aspiration artefact, $p<0.0001$. The authors concluded that the quality of biopsy cylinder and adequacy rate of the biopsy is comparable between both devices, however, the OnControl device showed more aspiration artefact.

Lynch et al (2015) performed a retrospective study to evaluate the quality and quantity of bone marrow aspirates and biopsy specimens obtained with the OnControl Bone Marrow System versus the standard manual method. A total of 136 cases (68 patients) were reviewed and compared using an unpaired t test. The study found that although longer core biopsy specimens were obtained by the OnControl Bone Marrow system, the manual method proved superior when the percentage and length of evaluable bone marrow were analyzed.

Bucher et al (2013) conducted a single-center, prospective, non-blinded randomized study to evaluate the diagnostic and clinical usefulness of a powered bone marrow biopsy device versus a standard manual device. Primary endpoints were biopsy quality and patient pain during the procedure. Fifty patients underwent a total of 60 procedures by 3 expert operators in a randomized stratified fashion. Baseline demographic and clinical parameters were similar in both groups. The usage of conscious sedation was similar between groups. Biopsy quality was rated ‘sufficient for diagnosis’ in 24/30 in the control group and 25/30 in the powered group ($p=0.74$). Biopsy cylinder length, procedure time, and patient reported pain during the procedure (T1), 15 min after the procedure (T2) and 3–5 days after the procedure (T3) there were comparable between groups. In the small subgroup of patients that did not receive conscious sedation (n=15; manual 6, powered 9) significantly lower median pain scores were observed with the powered system (median pain score 3 vs 7; $p=0.015$). Patients were satisfied with either device whether sedation was used (sedation: median 9 for both groups, range 3–10 (manual) and 0–10 (powered)) no sedation (median 8 (manual) vs 9 (powered)). The authors concluded that bone marrow biopsies taken with the manual or powered device produce similar technical and clinical results. In addition, the authors noted that “overall, at about 3 times of the cost of a manual device, the powered device offered very limited advantages.”

Voigt et al (2013) published a systematic review and meta-analysis of randomized trials. The objectives of the systematic review and meta-analysis were “to determine if the powered system

reduces patient pain and improves sample capture." A PubMed and Cochrane search for randomized controlled trials was conducted comparing the powered system with manual methods. Five randomized controlled trials were identified. Patient pain (measured via visual analogue scale (VAS)—100 point scale) was significantly reduced using the powered system: mean difference=−6.57; 95% CI −12.93 to −0.22; p=0.04. The relative reduction in pain was 17%–25% with the powered system. Sample biopsy size (length in mm) was also significantly increased with the powered system: mean difference=3.65 mm; 95%; CI 1.61 mm to 5.68 mm; p=0.0005. The relative increase in sample size was 33% with the powered system. Operator ease of use (as measured via VAS) and adverse events were similar. It was concluded that despite limited operator experience, patients experienced less pain and sample sizes were increased without an increase in adverse events with the powered system. If operator awareness and the overall use increases, the powered system may offer an option in obtaining samples. Additionally, the authors noted that "studies with experienced powered bone marrow biopsy system users should be undertaken to confirm and reinforce these findings."

Berenson et al (2011) published a manufacturer-sponsored randomized clinical trial comparing the OnControl battery-powered advantages over traditional manually-inserted needles in regard to length of procedure, patient pain, complications, user satisfaction and pathological analysis of the specimens. Ten sites randomized 102 adult patients requiring marrow sampling procedures (powered, n = 52; manual, n = 50). Visual Analog Scale (VAS) pain scores were captured immediately following the procedure and 1 and 7 days later. Procedure time was measured, and core specimens were submitted to pathology for grading.

The mean VAS scores for overall procedural pain were not significantly different between the arms (3.8 ± 2.8 for powered, 3.5 ± 2.3 for manual [p = 0.623]). A day later, more patients who underwent the powered procedure were pain-free (67%) than those patients in the manual group (33%; p = 0.003). One week later, there was no difference (83% for powered patients; 76% for manual patients.) Mean procedure time was 102.1 ± 86.4 seconds for the powered group and 203.1 ± 149.5 seconds for the manual group (p < 0.001). Pathology assessment was similar in specimen quality, but there was a significant difference in the specimen volume between the devices (powered: 36.8 ± 21.2 mm3; manual: 20.4 ± 9.0 mm3; p = 0.039).Two non-serious complications were experienced during powered procedures (4%); but none during manual procedures (p = 0.495).

The success rate of acquiring successful core biopsies was similar between the arms (powered: 90.4%; manual: 98.0%; p = 0.205). Assessment by pathology showed equivalence in core specimen quality parameters and length and width, but the specimen volume was larger in the Powered group (36.8 mm3 ± 21.2) than the Manual group (20.4 mm3 ± 9.0; p = 0.039). Although the authors agreed that length is generally the criteria used for determining the ideal size of a bone marrow core specimen, they opined that specimen volume may be a more pertinent factor in tissue analysis. There was no difference between the two devices for operator satisfaction, nor for patient satisfaction.

The researchers concluded that the powered device delivers larger volume bone marrow specimens for pathology evaluation. In addition, bone marrow specimens were secured more rapidly, although this was a difference measured in seconds. The researchers added that "further study is needed to determine if clinicians more experienced with the powered device will be able to use it in a manner that significantly reduces needle insertion pain; and to

compare a larger sample of pathology specimens obtained using the powered device to those obtained using traditional manual biopsy needles."

Reed et al (2011) sought to compare a novel bone marrow device with the standard marrow needle in a manufacturer-funded, prospective randomized study in a teaching hospital. A total of 54 bone marrow specimens were obtained; 27 were obtained manually and 27 were obtained with a powered device. There was statistical homogeneity between the 2 groups. Compared to the powered device method, which had a mean procedure time of 175 seconds, the manual method had a mean procedure time of 292 seconds, approximately 2 minutes longer. Patient-reported pain scores showed a trend favoring the powered device method, but the difference was not significant (P=0.11). A similar result was reported by Berenson et al, who concluded that the overall patient-reported pain score was due primarily to the sharp pain associated with marrow aspiration and that patient-reported pain would not be expected to vary among the use of different needles.

In another manufacturer-funded study by Swords et al (2011), patients from 2 large medical centers were randomized into powered (n=25) or manual (n=25) groups. A VAS pain score was recorded immediately following skin puncture and again at the end of the procedure for each patient. The procedure time was measured from skin puncture to core specimen acquisition. Pathologic assessment of 30 randomized samples was carried out. Operator satisfaction with devices was measured on a scale of 0-10, with 10 as the highest rating.

According to the researchers, "The powered system was superior to the manual system with respect to patient perceived pain from needle insertion (2.6 ± 2.0 vs. 4.1 ± 2.5, p=0.022) and procedural time (100.0 ± 72.8 s vs. 224.1 ± 79.0 s, p<0.001). Overall pain scores at the end of both procedures were comparable (3.2 ± 2.2 vs 3.8 ± 3.0, p=0.438). No complications were observed in either arm of the study. Blinded pathologic analysis of the specimens retrieved revealed that cores obtained using the powered system were longer and wider than those obtained using the manual technique (25.4 ± 12.3 mm^2 vs. 11.9 ± 5.6 mm^2, p=0.001). For marrow aspiration, no difference was seen between groups for clot/particle spicules or smear spicules. Operator assessment favored the use of the powered device."

Cohen and Gore (2008) evaluated a powered bone marrow aspiration device for use in diagnosing disease and monitoring disease course and medical therapy. Data collection included insertion success, time to insertion and complications. Patient pain levels were rated 0-10 (10=extreme pain). Device operators rated ease of use of the device 0-10 (10=outstanding). There were 55 patients from 3 centers. Successful insertion and aspiration were achieved in 54 out of 55 patients (98.1%). Mean insertion time was 4.9±3.0 seconds and there were no complications. The mean insertion pain score was 2.5±2.2, and the mean aspiration pain score was 3.7±2.5. The 6 operators rated the ease of use of the device at a mean score of 8.3±1.7. The researchers concluded that the powered aspiration device is safe and effective for bone marrow aspirations.

No studies were found that evaluated that assessed the long-term patient clinical outcomes. The Berenson study followed patients for 1 week post procedure, but there were no clinical studies that evaluated patient outcomes beyond 1 week. The published studies were primarily sponsored or funded by the manufacturer. Limitations included lack of blinding of patients, operators, and observers and the absence of blinded comparison studies of the pathologic quality of the powered device specimens versus manually obtained samples. Although these

devices appear to be relatively safe and clinicians appear satisfied with its ease of use, larger clinical trials are needed to evaluate the efficacy and safety of powered bone marrow biopsy systems in different patient populations. Additional studies are needed to compare the clinical utility and diagnostic superiority of this method versus the standard methods of bone marrow aspiration and biopsy.

The Michigan Society of Hematology and Oncology provided the following statement: “Given the limited use of the device, it is difficult to advocate at this time that the device meets current acceptable standards of care for performing bone marrow aspirate and biopsies. With further exposure of the device to the oncology community, a more definitive recommendation may be made in the future.”

Government Regulations

National:

There is no National Coverage Determination (NCD) identified for the use of powered bone marrow aspiration systems for obtaining bone marrow biopsies.

Effective October 1, 2011, CMS issued a pass-through code (C1830) for this device under Medicare's hospital outpatient prospective payment system (OPPS).

Local:

There is no local coverage determination for this device.

(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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7. Lynch, DW et al, “Adequacy of powered vs manual bone marrow biopsy specimens: a retrospective review of sequential marrow aspirates and biopsies in 68 patients,” Am J Clin Pathol, 2015, Vol. 143, No. 4, pp. 535-539.
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10. Swords, Ronan T., et al, “A prospective randomised study of a rotary powered device (OnControl) for bone marrow aspiration and biopsy,” *Journal of Clinical Pathology,* May 2011.
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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through March 3, 2023, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
3/1/12	12/13/11	12/21/11	Joint policy established
5/1/13	2/19/13	3/4/13	Routine maintenance
9/1/14	6/20/14	6/23/14	Routine maintenance
11/1/15	8/24/15	9/14/15	Routine maintenance
11/1/16	8/16/16	8/16/16	Routine maintenance
11/1/17	8/15/17	8/15/17	Routine maintenance
11/1/18	8/21/18	8/21/18	Routine maintenance
7/1/19	4/16/19		Routine maintenance
7/1/20	4/14/20		Routine maintenance
7/1/21	4/20/21		Routine maintenance
7/1/22	4/19/22		Routine maintenance
7/1/23	4/18/23		Routine maintenance (slp) Vendor Managed: N/A

Next Review Date: 2nd Qtr, 2024

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: POWERED BONE MARROW ASPIRATION AND BIOPSY SYSTEMS

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.