I. **Policy**

Minimally invasive direct coronary artery bypass graft surgery (MIDCAB) may be considered **medically necessary**.

Other techniques for minimally invasive coronary artery bypass graft surgery, including but not limited to port access coronary artery bypass (PACAB), hybrid CABG, or total endoscopic coronary artery bypass (TECAB) techniques, are **investigational**, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with the procedure.

II. **Product Variations**

[N] Capital Cares 4 Kids  
[N] PPO  
[N] HMO  
[N] SeniorBlue HMO  
[N] SeniorBlue PPO  

[Y] = Standard product coverage varies from application of this policy, see below

[N] Indemnity  
[N] SpecialCare  
[N] POS  
[N] FEP PPO
III. DESCRIPTION/BACKGROUND

There are currently variations on techniques that are classified as “minimally invasive” coronary artery bypass graft (CABG) surgery. The surgery can be done under direct vision, with a mini-sternotomy or a mini-thoracotomy approach. These types of direct procedures have been termed minimally invasive direct coronary artery bypass (MIDCAB). MIDCAB is performed without cardiopulmonary bypass by slowing the heart rate to 40 beats per minute to minimize motion in the surgical field. The performance of a coronary bypass on a beating heart increases the technical difficulty of the procedure, particularly in terms of the quality of the vessel anastomosis. In MIDCAB, the predominant re-anastomosis performed uses the native internal mammary artery to bypass the left anterior descending coronary (LAD) artery. Bypass of the right coronary artery may also be possible in patients with suitable anatomy.

The surgery can also be performed endoscopically, whereby the internal structures are visualized on a video monitor, and the entire procedure is performed without direct visualization of the operative field. Cardiopulmonary bypass may or may not be used with this technique. This variation of minimally invasive CABG is called port access coronary artery bypass (PACAB) or total endoscopic coronary artery bypass (TECAB). Using this approach, theoretically all sides of the heart can be approached. In most instances, only a single bypass of the LAD artery is performed, although multi-vessel bypass of the left and right coronary artery has been performed.

Regulatory Status

Minimally invasive CABG is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration (FDA). The procedure can be performed with conventional instruments or instruments specifically designed for this purpose. Special instruments designed for these procedures are subject to FDA marketing clearance, and several manufacturers have received 510(k) clearance to market devices intended for use in minimally invasive CABG. One such device for computer-assisted surgery or robotic technology is the da Vinci® system (Intuitive Surgical, Inc., Mountain View, CA). The da Vinci system received 510(k) marketing clearance from the FDA in 2004 for assisting in coronary artery bypass surgery.

IV. RATIONALE

MIDCAB

Since the TEC Assessment, there has been a shift in emphasis from comparing MIDCAB to open CABG to comparing MIDCAB with PTCA and stenting for patients with isolated stenosis of the left anterior descending (LAD) artery. Over this period of time, PTCA and stenting became more established at treating LAD lesions, and open CABG for this indication became less frequent.
At least 5 randomized controlled trials (RCTs) have been published that compare MIDCAB for isolated LAD lesions with PTCA and stenting. These trials were all relatively small, ranging from 100 to 220 enrolled patients. They were performed in Europe or Asia, with no RCTs having been completed in the United States. Only 1 of these 5 trials used drug-eluting stents; the other trials used bare metal stents in comparison to MIDCAB.

In the largest RCT completed to date, Diegeler et al. (3) randomly assigned 220 patients to MIDCAB or PTCA plus stenting and reported outcomes up to 6 months following treatment. In the MIDCAB group, 2 deaths occurred within 30 days of surgery compared with none for the PTCA group (p=0.99). At 6 months, the combined rate of death and myocardial infarction (MI) was 6% for MIDCAB and 3% for PTCA (risk ratio [RR]: 2.33 for MIDCAB); this difference had a wide confidence interval (CI) and was not statistically significantly different from PTCA (95% CI: 0.34–43.73, p=0.50). A greater percentage of MIDCAB patients were angina-free after surgery (79% vs. 62%, respectively, p=0.03), and the MIDCAB patients required fewer reinterventions at 6 months (5% vs. 27%, respectively, p=0.02).

Thiele et al. (4) published a 5-year follow-up of this RCT comparing clinical outcomes between groups. Mortality was similar in patients who had undergone MIDCAB and those who had undergone percutaneous coronary intervention (PCI; 12% vs. 10%, respectively, p=0.5). There were also no differences in cardiac death (5% vs. 4%, respectively, p=0.60) or MI (7% vs. 5%, respectively, p=0.71). Target vessel revascularization was significantly lower for the MIDCAB group compared to PCI (10% vs. 32%, respectively, p less than 0.001).

Drenth and colleagues reported the results of a trial that randomly assigned 102 patients with isolated high-grade stenosis of the proximal LAD to either MIDCAB or stenting. (5) At 6 months, quantitative coronary angiography showed an anastomotic stenosis rate of 4% after MIDCAB compared to 29% after stenting, although the clinical outcomes in the 2 groups were similar. Two patients died after MIDCAB compared to none after stenting.

Reeves et al. randomly assigned 100 patients to MIDCAB or PTCA and found no significant differences when evaluating angina symptoms or disease-specific or generic quality of life. (6) The authors estimated 12-month cumulative hazard rates for MIDCAB were 7.1% and 9.2% for PTCA and concluded that there was no evidence that MIDCAB was more effective than PTCA.

Kim et al. randomly assigned 100 patients with LAD stenosis greater than 70% and stable or unstable angina to MIDCAB or PTCA with bare metal stents. (7) There were a small number of in-hospital events, with no difference between groups. At 1 year, mortality was equal at 4%, and more patients in the PCI group required target vessel revascularization (7 vs. 1, respectively, p less than 0.001).

Hong et al. enrolled 189 symptomatic patients with isolated high-grade stenosis of the LAD artery to MIDCAB or PCI with drug-eluting stents. (8) The in-hospital complication and death rates did not differ among the groups. At 6 months’ follow-up, there were no significant differences in death, MI, or target vessel revascularization.
Cisowski et al. randomly assigned 100 patients with Canadian Cardiovascular Society (CCS) angina class II-IV and isolated stenosis of the LAD of greater than 70% to MIDCAB or PCI with bare metal stenting. (9) At 30-day follow-up, there were no deaths and 1 MI in the PCI group. Freedom from angina at 30 days was 98% in the MIDCAB group and 88% in the PCI group, a difference that was not statistically significant. At 6 months, fewer patients in the MIDCAB group required target vessel revascularization (2% vs. 18%, respectively, p less than 0.01). At 1-year follow-up, there was no difference in mortality or other adverse cardiac events between groups. Freedom from angina was greater in the MIDCAB group (100% vs. 75%, respectively, p less than 0.01).

None of the trials reviewed were designed or powered to test equivalence between groups; therefore, studies reporting equivalent outcomes are prone to a type II error. The main limitation to this evidence is the possibility of a type II error, i.e., that these trials do not contain adequate power to demonstrate a meaningful clinical difference that might be present. In addition, it should also be noted that drug-coated stents, designed to reduce the restenosis rate, are now commercially available and widely used. Thus, the restenosis rates associated with bare metal stenting reported in these trials may not reflect the current practice. It is notable that the only trial that used drug-eluting stents (8) reported no difference in target vessel revascularization at 6 months.

A number of meta-analyses have been published analyzing this body of RCTs (10-12). While the studies included varied slightly, the conclusions of these analyses were relatively consistent. None of the analyses established any perioperative or in-hospital differences in mortality, MI, or other adverse events. Even with pooling of the studies, there were only a small number of clinical events to be compared, and these meta-analyses were not likely to have adequate power to detect small- to moderate-sized differences in perioperative outcomes. Similarly, none of the meta-analyses demonstrated any differences in long-term clinical adverse events, such as mortality or MI. All 3 meta-analyses concluded that medium- to long-term target vessel revascularization was less commonly required for patients receiving MIDCAB than for patients receiving PCI, and 2 concluded that angina recurrence was less for the MIDCAB group. Accordingly, combined outcomes that included revascularization and/or angina recurrence were significantly better for the MIDCAB group while combined outcomes that did not include revascularization or angina recurrence showed no significant difference between groups. As noted previously, only 1 of the randomized trials used drug-eluting stents.

In a randomized trial using non-inferiority analysis from Europe, Thiele and colleagues evaluated MIDCAB versus sirolimus-eluting stents (SES) for isolated proximal left anterior-descending artery (LADA) disease. (13) Sixty-five patients were randomly assigned to each group between 2003 and 2007. Approximately 25% of both groups had diabetes; average age was 66 years, and 70% were males. In total, 3.1% of stent patients had at least 1 postprocedure event compared to 16.9% after MIDCAB (p=0.02). Median length of hospitalization was 3 days in the stenting group and 13 days in the MIDCAB patients (p less than 0.001). At 12 months, the rate of major adverse cardiac events (MACE) was equivalent; 7.7% for stenting
and 7.9% for MIDCAB. There were no cardiac deaths in either group at 12 months. There were more revascularizations in the stent group (6.2% vs. 0%, respectively), but more acute myocardial infarctions (all within 30 days) in the MIDCAB group (1.5% vs. 7.7%, respectively). The authors concluded that at 12 months, SES is noninferior to MIDCAB with respect to MACE at a similar relief in clinical symptoms.

No new comparative trials were identified during the 2010 literature search. Kofidis and colleagues published follow-up on 390 patients who had MIDCAB for LAD coronary artery disease beginning in 1996. (14) The average age was 61 years [69% were males. Early postoperative mortality was 0.8% and MI occurred in 1.3%. The authors report a 97.5% patency rate based on 238 of the 390 patients (61%) and that 74% had no stenosis at late angiography based on results for 78 patients. The authors concluded that MIDCAB is a safe procedure with long-term anastomotic patency rates comparable with those of open-chest left-internal-mammary-artery to LAD bypass.

Kettering performed a literature search for all published outcome studies of MIDCAB grafting for the period from January 1995 through October 2007. (15) Seventeen articles were identified for this analysis. The data presented in the studies were analyzed with regard to clinical and angiographic results. Early and late (more than 30 days after MIDCAB) death rates were 1.3% (51/4,081 patients) and 3.2% (130/4,081 patients), respectively. The infarct rate was 0.8% (32/4,081 patients; non-fatal MI). Other minor or major complications (e.g., reoperation for management of bleeding, chest wound problems, arrhythmias, cerebrovascular accident, pericardial effusion, pulmonary complications) were reported in 781 cases. The conversion rate to sternotomy/cardiopulmonary bypass was 1.8% (74/4,081 patients). A re-intervention due to graft failure was necessary in 134/4,081 patients (3.3%). A total of 2,556 grafts were studied angiographically immediately after surgery. One hundred and six grafts (4.2%) were occluded, and 169 grafts (6.6 %) had a significant stenosis (50-99%, respectively). At 6-month follow-up, 445 grafts were studied angiographically. Sixteen grafts (3.6%) were occluded, and 32 grafts (7.2%) had a significant stenosis. The authors concluded that clinical outcomes and immediate graft patency after MIDCAB are acceptable; however, long-term follow-up results and further randomized prospective clinical trials comparing this technique with standard revascularization procedures in large patient cohorts are needed.

In summary, the data from these clinical trials demonstrate that MIDCAB can be performed with low surgical morbidity and mortality and with a high percentage of patients reporting relief from angina. Compared with PTCA and stenting (bare metal), MIDCAB reduces the future occurrence of angina and reduces the need for future revascularization procedures. However, the data do not demonstrate differences in other clinical outcomes such as MI or mortality; but, studies were not large enough to detect potential meaningful differences. The relevance of decreased angina and revascularization to current clinical practice is lessened by the fact that the majority of these trials employed bare metal stents, as opposed to drug-eluting stents.
PACAB, TECAB, and Hybrid CABG

There is scant evidence from clinical trials on the impact of PACAB or total endoscopic CABG (TECAB, an alternative term for PACAB) on health outcomes. Dogan and colleagues reported on the results of a trial that randomly assigned 40 patients who required multivessel revascularization to undergo either conventional CABG or PACAB. (16) However, this study only reported short-term outcomes of the procedure, i.e., intraoperative time, cardiopulmonary bypass time, hospital stay, etc., and not long-term outcomes.

TECAB is an alternative name for PACAB. Some centers have instituted robotic-assisted TECAB with the da Vinci® robotic system, which can be performed either with cardiopulmonary bypass (on-pump) or on the beating heart (off-pump). To date, studies of this procedure consist of pilot studies intended to demonstrate feasibility, (17) and a number of single-arm case series that report clinical outcomes. (18-20) Some of these series report outcomes that may be comparable to conventional CABG, (18) but others report clinical outcomes that may be inferior to those expected with conventional CABG. (20) No clinical trials were identified that directly compare TECAB with alternatives such as conventional CABG, MIDCAB, or PTCA.

A multicenter, randomized trial was conducted in the VA system comparing on-pump to off-pump CABG. (21) This trial involved randomly assigning 2,203 patients who were scheduled for urgent or elective CABG to an on-pump or off-pump procedure. In some cases, complete revascularization was performed for all areas of the heart. About two-thirds of cases involved intervention on 3 vessels. At 1 year of follow-up, patients in the off-pump group had worse composite outcomes and poorer patency than those in the on-pump group. Fewer grafts were completed than had been planned for those in the off-pump group. In this study, there were no differences in neuropsychologic outcomes. While this study does not support use of off-pump CABG, a number of concerns have been raised about this study, including the relative level of skill in those doing the on-pump compared to the off-pump procedures. (22)

Another variation on PACAB is “hybrid” or “integrated” CABG, in which PACAB is combined with PTCA and stenting to treat multivessel CAD. Studies to date on this approach consist mainly of small case series intended to demonstrate the feasibility and safety of this procedure. (23)

Thus, none of the MEDLINE searches of peer-reviewed literature for the period of April 2005 through January 2010 identified clinical trials that would alter the conclusions reached above for either PACAB, TECAB (including robotically assisted), or hybrid CABG. As a result, the evidence remains insufficient to determine whether PACAB, TECAB, and/or hybrid CABG improve outcomes compared to conventional procedures. The policy statement for these procedures therefore remains unchanged. Additional randomized comparative studies are needed that compare the relevant short- and long-term outcomes from these new techniques with outcomes obtained using the current approaches.
Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2010

In response to requests, input was received from 1 physician specialty society and 4 academic medical centers while this policy was under review in 2010. All of those providing input agreed with the conclusions of this policy regarding TECAB. The MIDCAB procedure was supported by a majority of those providing input.

2014

Review of the literature revealed no new information that would alter the conclusions reached above. Therefore, the policy statement is unchanged.

Summary

Given the clinical data summarized earlier in this document and the clinical support, MIDCAB (CABG with anastomoses hand sewn under direct vision) may be considered medically necessary. Given both the limited clinical data and the lack of clinical support, other minimally invasive approaches to CABG, such as TECAB are considered investigational.

Clinical Trials

A search for relevant clinical studies of these procedures identified 1 trial. It is a non-comparative trial involving 50 patients, entitled Coronary Stenting and Coronary Bypass Grafting [TECAB] at the Same Time in a Specialty Built Operating Room. (24) This trial is being conducted by the Lawson Health Research Institute under the Canadian Foundation for Innovation, Ontario Innovative Trust. While results were expected in early 2009, the information on clinicaltrials.gov was last updated October 2008. No U.S.-based trials were identified.
V. DEFINITIONS

ANASTOMOSIS refers to a natural communication between two vessels; may be direct or by means of connecting channels.

CARDIOPULMONARY BYPASS is a procedure used in heart surgery in which the blood is diverted from the heart and lungs by means of a pump oxygenator and returned directly to the aorta.

ENDOSCOPY refers to inspection of body organs or cavities by use of an endoscope.

HYBRID OR INTEGRATED CABG is a variation on PACAB.

PACAB is combined with PTCA and stenting to treat multivessel coronary artery disease.

STERNOTOMY refers to the operation of cutting through the sternum (breastbone).

TECAB (total endoscopic coronary artery bypass) is an alternative name for PACAB (port access coronary artery bypass). Some centers have instituted robotic-assisted TECAB with the daVinci® robotic system, which can be performed either with cardiopulmonary bypass (on-pump) or on the beating heart (off-pump).

THORACOTOMY refers to surgical incision of the chest wall.

V. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

VI. DISCLAIMER

Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.
VII. REFERENCES


Other:
VIII. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

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<th>CPT Codes®</th>
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<td>MIN INVASV DIR CAB SURG; ART GFT 1 COR ART GFT</td>
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<td>S2206</td>
<td>MIN INVASV DIR CAB SURG; ART GFT 2 COR ART GFT</td>
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<td>S2207</td>
<td>MIN INVAS DIR CAB; VEN GFT ONLY 1 COR VEN GFT</td>
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<td>MIN INVASV DIR CAB SURG; 2 ART GFT&amp;1 VENUS GFT</td>
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<td>414.00-414.07</td>
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*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

The following ICD-10 diagnosis codes will be effective October 1, 2015

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*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.
# IX. POLICY HISTORY

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<td>CAC 5/26/09</td>
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<td>CAC 7/26/11</td>
<td>CAC 7/26/11 Adopt BCBSA. CBC considered MIDCAB medically necessary before BCBSA changed their policy effective 10/8/10. Hybrid CABG is a newly added investigational procedure added to list. No previous policy statement addressing hybrid CABG.</td>
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<td>7/22/13 Admin coding review complete--rsb</td>
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<tr>
<td>CAC 9/24/13</td>
<td>CAC 9/24/13 Consensus review. References updated; no changes to the policy statements.</td>
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