Off-pump coronary artery bypass

Background

Coronary artery bypass grafting (CABG) is an open-heart procedure designed to reroute blood flow around blockages or obstructions in the coronary arteries. Off-pump coronary artery bypass surgery (OPCAB) is a variation on the traditional procedure. It differs because surgeons perform the procedure without using the heart-lung machine to take over the heart’s function. Instead, the heart continues to beat and surgeons complete the graft using stabilizers to hold segments of the beating heart still, according to the Society for Thoracic Surgery (STS).

To perform the bypass, a cardiothoracic surgeon will open the chest using an incision called a median sternotomy, allowing him or her access to the heart and aorta. Originally, surgeons only used the saphenous vein from the leg for the procedure, but later discovered that using another artery from inside the chest wall provided advantages. Both are used in the procedure today, and sometimes the surgeon will also opt to use an artery from the patient’s wrist, according to the National Institutes for Health.

OPCAB may provide advantages over traditional bypass surgery to some patients with coronary artery disease, according to the Cleveland Clinic, including those who have:

➤ Heavy aortic calcification
➤ Carotid artery stenosis
➤ A history of stroke
➤ Compromised pulmonary function
➤ Compromised renal function

The main advantage of OPCAB over the traditional bypass procedure is that physicians believe it may cut down on cognitive side effects that temporarily affect some patients after they are put on the heart-lung machine.

According to the Cleveland Clinic, researchers have found that while outcomes for both types of bypass surgeries were excellent, the OPCAB patients had fewer cognitive side effects, reduced kidney failure, lower red blood cell usage, and fewer infections.

However, studies have also shown that OPCAB patients had more cases of “incomplete revascularization” (meaning full blood flow wasn’t restored) than traditional bypass patients.

There are alternatives to bypass surgery, including balloon angioplasty, lifestyle changes, and medical therapy, according to the National Heart Lung and Blood Institute.
**Involved specialties**

Cardiothoracic and thoracic surgeons

**Positions of specialty boards**

*ABS*

The American Board of Surgery (ABS) offers a joint certification program in general and thoracic surgery, which includes four years of surgery followed by three years of thoracic surgery in the same institution. Joint training programs must be approved by the Residency Review Committee for Surgery and the Residency Review Committee for Thoracic Surgery (RRC-TS) before implementation.

The joint training pathway is not quicker than traditional surgery certification, but it does have different clinical assignments during the last 24 months of the program, which must include rotations within general surgery that are applicable to thoracic surgery.

Of the first 48 months of surgical residency, 36 months must be spent in the following content areas:

- Abdomen and its contents
- Alimentary tract
- Breast, skin, and soft tissue
- Endocrine surgery
- Organ transplantation
- Pediatric surgery
- Surgical critical care
- Surgical oncology (including head and neck surgery)
- Trauma/burns and acute care surgery
- Vascular surgery

These 36 months can also be spent in secondary areas such as thoracic surgery, plastic and reconstructive surgery, and endoscopy, or in laparoscopy and advanced laparoscopy.

The final 24 months of surgery residency should include cross-training in the following content areas, which have been identified as areas of expertise specifically applicable to thoracic surgery education:

- Alimentary tract
- Organ transplantation
- Surgical critical care
- Vascular surgery
- Endoscopy
- Thoracic surgery
- Advanced laparoscopy
Candidates must also spend 12 of the 24 months of PGY-4 and PGY-5 as chief resident in surgery, with the majority of the chief year spent in PGY-5. Candidates should not devote more than four of the 24 months in PGY-4 and PGY-5 exclusively to any one content area.

Candidates should spend at least eight but not more than 12 months in areas defined as important to the preparation of a thoracic surgeon and should ensure that the majority of thoracic surgery preparation occurs in PGY-4; however, PGY-5 is permissible as well. Candidates must spend all 24 months of PGY-4 and PGY-5 in clinical assignments, not in research rotations.

Residents who complete necessary requirements are eligible for certification in surgery at the end of PGY-5 and for certification in thoracic surgery at the end of PGY-7.

ABS does not publish requirements specific to OPCAB.

**ABTS**

The American Board of Thoracic Surgery (ABTS) awards certification in thoracic surgery, which may be achieved by completing one of the following four pathways and fulfillment of the other requirements. These pathways must provide adequate education and operative experience in cardiovascular and general thoracic surgery.

➤ **Pathway One** is the successful completion of a full residency in general surgery approved by the Accreditation Council for Graduate Medical Education (ACGME), followed by the successful completion of an ACGME-approved thoracic surgery residency. Successful completion of a 4/3 general surgery/thoracic surgery joint training program approved by the ACGME fulfills the requirements of Pathway One.

➤ **Pathway Two** is the successful completion of a full residency in general surgery or cardiac surgery approved by the Royal College of Physicians and Surgeons of Canada (RCPSC), followed by the successful completion of an ACGME-approved thoracic surgery residency.

➤ **Pathway Three** is the successful completion of a six-year integrated thoracic surgery residency developed along guidelines established by the Thoracic Surgery Directors Association and approved by the ACGME (RRC-TS).

➤ **Pathway Four** is the successful completion of an ACGME-approved vascular surgery residency that can lead to primary certification followed by the successful completion of an ACGME-approved thoracic surgery residency.

Candidates must have knowledge of both normal and pathologic conditions of both cardiovascular and general thoracic structures, including congenital and
acquired lesions of both the heart and blood vessels in the thorax, as well as diseases involving the lungs, pleura, chest wall, mediastinum, esophagus, and diaphragm.

ATBS requires operative experience requirements including an annual average of 125 major operations performed by each resident. The total number of major cases varies based on the length of the training program.

ABTS does not publish requirements specific to OPCAB.

**AOBS**

The American Osteopathic Board of Surgery (AOBS) accepts certification for examination for osteopathic physicians who are specializing in general surgery and cardiothoracic surgery. Candidates for certification by the American Osteopathic Association (AOA) through AOBS must document the following:

➤ Graduation from an AOA-accredited college of osteopathic medicine.
➤ License or credentials to practice in the state or military jurisdiction where practice is conducted. The candidate must document evidence of an unrestricted license prior to taking an examination.
➤ Documentation that he or she conforms to the standards set forth in the Code of Ethics of the AOA.
➤ Membership in good standing of the AOA or the Canadian Osteopathic Association throughout the certification process. Following the examination process, if a candidate is found to be delinquent in his/her maintenance of membership and/or payment of membership dues, certification may be delayed.
➤ Satisfactory completion of an AOA-approved OGME-1.

For certification in general surgery, the candidate must complete four years of training in general surgery.

The requirement changes for candidates who began their residency training with the required OGME-1R internship year effective in the academic year 2008, who must have five years of training.

Candidates for certification in cardiothoracic surgery must have four years of training in general surgery followed by two years of training in cardiothoracic surgery. Candidates who began their residency training with the required OGME-1R internship year effective in the academic year 2008 must complete five years of training in general surgery followed by two years of training in cardiothoracic surgery. Cardiothoracic surgery candidates must pass the written and oral general surgery exams.

AOBS does not publish requirements specific to OPCAB.
Positions of societies, academies, colleges, and associations

STS/AATS

The STS and the American Association for Thoracic Surgery (AATS) do not publish credentialing or privileging criteria for physicians performing OPCAB. However, they do include information about OPCAB on their website for the Cardiothoracic Surgery Network (CTSNet), Inc., a nonprofit corporation jointly created by the STS, AATS, and the European Association for Cardio-thoracic Surgery. CTSNet also has participation agreements in place with 48 cardiothoracic surgical societies around the world, which use the website as their official online voice.

The website includes information about OPCAB, which is as follows:
➤ Beginning beating heart surgeons, or those who have performed less than 50 beating heart cases, should avoid operating on patients with any of the following risk factors:
  − Cardiomegaly (cardiothoracic ratio > 0.7), as this makes exposure of lateral and inferior walls of the left ventricle difficult
  − Small (< 1.5 mm diameter), intramyocardial, or diffusely diseased target vessels
  − Hemodynamically unstable patients
  − Critical left main disease
  − Suffering or having recently suffered an acute myocardial infarction
  − Severe left ventricular dysfunction (left ventricle ejection fraction < 35%)
➤ Expert beating heart surgeons, or those who have performed more than 50 cases, should avoid OPCAB if multiple risk factors are present

CTSNet also offers the following additional tips on its website:
➤ Attention to detail is critical to success, as safety margin with OPCAB is reduced compared to traditional CABG.
➤ Intracoronary shunts are extremely useful in minimizing the amount of ischemia and improving the safety of the operation. Training institutions should use shunts to allow residents to be safely trained in OPCAB.
➤ Allow extra time to obtain the best presentation and stabilization for obtuse marginal vessels. Do not compromise exposure. If adequate exposure cannot be obtained, the anastomosis should not be compromised and the traditional approach should be used.
➤ A CO2 blower is crucial for beating heart surgery but has to be used very sparingly, at a flow rate not exceeding 5 L/min, to prevent damage to the coronary endothelium. Avoid directing the gas jet directly into the vessel lumen to prevent gas embolization.
➤ Heparin reversal is not mandatory. Anastomosis of the obtuse marginal vessels is easier from the left side of the table.
➤ Place temporary pacing wires before occluding the right coronary artery proximal to the bifurcation to manage possible A-V block.
**ACGME**

The ACGME publishes *Program Requirements for Graduate Medical Education in Thoracic Surgery*. Thoracic surgery training includes operative, perioperative, and critical care of patients with pathologic conditions within the chest.

Thoracic surgery education can be in one of several formats:

- The independent format, which includes two years of thoracic surgery education following the completion of an ACGME- or RCPSC-approved surgical residency. Three-year programs must be approved by the ACGME review committee.

- A joint surgery/thoracic surgery program, which stipulates that all seven years of the program must be completed in the same institution. After completing the program, the candidate can apply for both surgery and thoracic surgery certification.

- An integrated program, which includes six years of thoracic surgery education undertaken after the candidate has received his or her MD or DO degree from an accredited institution. The candidate must document six years of clinical thoracic surgery education with a minimum of 24 months and a maximum of 36 months of the program must include core surgical education, including pre- and postoperative evaluation and care. The rest of the curriculum must include education in:
  - Oncology
  - Transplantation
  - Basic and advanced laparoscopic surgery
  - Surgical critical care and trauma management
  - Thoracic surgery
  - Adult and congenital cardiac surgery

The last year of the program must include chief resident responsibility on the thoracic surgery service at the primary clinical site or at an integrated site.

Candidates for certification in thoracic surgery should have a minimum of 125 major operative cases. The cases should have the appropriate complexity and should be distributed throughout various categories of procedures, including:

- Lungs
- Pleura
- Chest wall
- Esophagus
- Mediastinum
- Diaphragm
- Thoracic
- Aorta and great vessels
- Congenital heart anomalies
- Valvular heart diseases
- Myocardial revascularization
Candidates should also have the following educational experiences:

➤ Cardiac pacemaker implantation
➤ Mediastinoscopy
➤ Pleuroscopy
➤ Flexible and rigid esophagoscopy and bronchoscopy
➤ Endoscopic ultrasound
➤ Endoscopic approaches to thoracic and esophageal diseases
➤ Multidisciplinary approaches to the treatment of thoracic malignancy
➤ Experience in endovascular stents (for residents admitted on or after July 1, 2007)

ACGME does not publish requirements specific to OPCAB.

**AOA**

The AOA publishes basic standards for surgical residency programs in both general and surgical specialties. Cardiothoracic residency programs should be two years long. Residents should have first successfully completed an AOA-approved general surgery residency program, which includes an OGME-1R year.

No more than a total of six months of clinical training should take place outside the primary training institution. Short courses of two weeks or less do not apply to the six-month limit.

The final twelve months of the two-year program must be spent as chief resident in approved institutions, under supervision, demonstrating advanced-level responsibilities for complete cardiothoracic surgical patient management.

The cardiothoracic surgery curriculum must meet or exceed the American College of Osteopathic Surgery model curriculum and must include the following structured learning experiences:

➤ Preoperative, intraoperative, and postoperative care of patients with diseases of the heart and great vessels; lung, pleura, and trachea; and esophagus, mediastinum, diaphragm, and chest wall
➤ Cardiopulmonary bypass physiology and mechanics; pulmonary function examination; noninvasive peripheral vascular examination; chest x-ray, MRI, and CT/PET scan interpretation; cardiac catheterization interpretation; cardiothoracic critical care management to include ventilator management; fluid and electrolyte management; clinical hematology, coagulation, and blood component replacement therapy; pharmacological and mechanical-assisted management of hemodynamic instability and support; and cancer chemotherapy and radiation therapy

Electives in organ transplantation and mechanical cardiac assist devices are highly desirable.
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Resident training should include sufficient scope, volume, and variety of clinical experience in cardiothoracic surgery. The program should prepare residents to successfully complete a program in cardiothoracic surgery and to qualify for entrance into the certification process by the AOBS through one of two primary pathways; a cardiothoracic surgery pathway or a general thoracic surgery pathway.

Each resident must also document participation in 255 major surgical procedures, performed by the resident as surgeon under supervision, including 150 adult cardiac procedures.

Positions of subject matter experts

**Michael E. Halkos, MD**
**Atlanta**

According to Michael E. Halkos, MD, assistant professor of surgery at Emory University School of Medicine in Atlanta, OPCAB is typically performed by cardiothoracic surgeons. There is no specific training related to OPCAB, aside from residency training, and this procedure is not part of the ACGME curriculum. “Typically surgeons learn how to perform the procedure in a stepwise progression,” he says. “First they learn to use the heart-lung machine, letting the heart beat. Then they might perform a procedure on the arteries on the front of the heart, which are typically easier to perform bypass surgery on than those arteries on the side and the back of the heart.”

Physicians should perform at least 50 cases to become proficient in this procedure and an additional 30–50 each year to maintain competence, says Halkos.

Credentialing staff looking at this procedure should be certain to look for outcomes, for both this procedure and for traditional coronary bypass surgery as well, he says.

**Valluvan Jeevanandam, MD**
**Chicago**

According to Valluvan Jeevanandam, MD, professor of surgery, chief of cardiac and thoracic surgery at the University of Chicago, and chief of cardiac and thoracic surgery at The University of Chicago Medicine, OPCAB procedures are typically performed by cardiothoracic surgeons. Physicians have to go through a formal residency training program to perform the procedure and should be board certified or board eligible.

“There’s really no course on off-pump surgery, you really just have to do it,” he says.
The procedure used to be more popular in the past, but increasingly physicians are opting to place stents as a less-invasive alternative.

While traditional bypass procedures are part of the ACGME curriculum, OPCAB is not specifically mentioned, he says. Medical devices are used in OPCAB procedures, including devices to stabilize the blood vessels, and companies will supply a proctor to provide training.

“In my opinion a physician should perform at least 25 procedures to become competent,” says Jeevanandam. Because the number of these procedures being performed is on the decline, 15 procedures a year is sufficient for a physician to maintain his or her skill level, he says.

Credentialing staff should look not only at OPCAB procedures but also at traditional bypass procedures performed. They should also make sure that the procedure is performed with a competent anesthesiologist, because providing anesthesia for this procedure is much more complex than for other procedures.

**CMS**

CMS has no formal position concerning the delineation of privileges for OPCAB. However, the CMS *Conditions of Participation (CoP)* define a requirement for a criteria-based privileging process in §482.22(c)(6) stating, “The bylaws must include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.”

§482.12(a)(6) states, “The governing body must assure that the medical staff bylaws describe the privileging process. The process articulated in the bylaws, rules or regulations must include criteria for determining the privileges that may be granted to individual practitioners and a procedure for applying the criteria to individual practitioners that considers:

➤ Individual character
➤ Individual competence
➤ Individual training
➤ Individual experience
➤ Individual judgment

The governing body must ensure that the hospital’s bylaws governing medical staff membership or the granting of privileges apply equally to all practitioners in each professional category of practitioners.”

Specific privileges must reflect activities that the majority of practitioners in that category can perform competently and that the hospital can support. Privileges are not granted for tasks, procedures, or activities that are not conducted within the hospital, regardless of the practitioner’s ability to perform them.
Each practitioner must be individually evaluated for requested privileges. It cannot be assumed that every practitioner can perform every task, activity, or privilege specific to a specialty, nor can it be assumed that the practitioner should be automatically granted the full range of privileges. The individual practitioner’s ability to perform each task, activity, or privilege must be individually assessed.

CMS also requires that the organization have a process to ensure that practitioners granted privileges are working within the scope of those privileges.

CMS’ CoPs include the need for a periodic appraisal of practitioners appointed to the medical staff/granted medical staff privileges (§482.22[a][1]). In the absence of a state law that establishes a time frame for the periodic appraisal, CMS recommends that an appraisal be conducted at least every 24 months. The purpose of the periodic appraisal is to determine whether clinical privileges or membership should be continued, discontinued, revised, or otherwise changed.

**The Joint Commission**

The Joint Commission has no formal position concerning the delineation of privileges for OPCAB. However, in its *Comprehensive Accreditation Manual for Hospitals*, The Joint Commission states, “The hospital collects information regarding each practitioner’s current license status, training, experience, competence, and ability to perform the requested privilege” (MS.06.01.03).

In the introduction for MS.06.01.03, The Joint Commission states that there must be a reliable and consistent system in place to process applications and verify credentials. The organized medical staff must then review and evaluate the data collected. The resultant privilege recommendations to the governing body are based on the assessment of the data.

The Joint Commission introduces MS.06.01.05 by stating, “The organized medical staff is responsible for planning and implementing a privileging process.” It goes on to state that this process typically includes:

- Developing and approving a procedures list
- Processing the application
- Evaluating applicant-specific information
- Submitting recommendations to the governing body for applicant-specific delineated privileges
- Notifying the applicant, relevant personnel, and, as required by law, external entities of the privileging decision
- Monitoring the use of privileges and quality-of-care issues

MS.06.01.05 further states, “The decision to grant or deny a privilege(s) and/or to renew an existing privilege(s) is an objective, evidence-based process.”
The EPs for standard MS.06.01.05 include several requirements as follows:

- The need for all licensed independent practitioners who provide care, treatment, and services to have a current license, certification, or registration, as required by law and regulation
- Established criteria as recommended by the organized medical staff and approved by the governing body with specific evaluation of current licensure and/or certification, specific relevant training, evidence of physical ability, professional practice review data from the applicant’s current organization, peer and/or faculty recommendation, and a review of the practitioner’s performance within the hospital (for renewal of privileges)
- Consistent application of criteria
- A clearly defined (documented) procedure for processing clinical privilege requests that is approved by the organized medical staff
- Documentation and confirmation of the applicant’s statement that no health problems exist that would affect his or her ability to perform privileges requested
- A query of the NPDB for initial privileges, renewal of privileges, and when a new privilege is requested
- Written peer recommendations that address the practitioner’s current medical/clinical knowledge, technical and clinical skills, clinical judgment, interpersonal skills, communication skills, and professionalism
- A list of specific challenges or concerns that the organized medical staff must evaluate prior to recommending privileges (MS.06.01.05, EP 9)
- A process to determine whether there is sufficient clinical performance information to make a decision related to privileges
- A decision (action) on the completed application for privileges that occurs within the time period specified in the organization’s medical staff bylaws
- Information regarding any changes to practitioners’ clinical privileges, updated as they occur

The Joint Commission further states, “The organized medical staff reviews and analyzes information regarding each requesting practitioner’s current licensure status, training, experience, current competence, and ability to perform the requested privilege” (MS.06.01.07).

In the EPs for standard MS.06.01.07, The Joint Commission states that the information review and analysis process is clearly defined and that the decision process must be timely. The organization, based on recommendations by the organized medical staff and approval by the governing body, develops criteria that will be considered in the decision to grant, limit, or deny a request for privileges. The criteria must be consistently applied and directly relate to the quality of care, treatment, and services. Ultimately, the governing body or delegated governing body has the final authority for granting, renewing, or denying clinical privileges. Privileges may not be granted for a period beyond two years.
Criteria that determine a practitioner’s ability to provide patient care, treatment, and services within the scope of the privilege(s) requested are consistently evaluated.

The Joint Commission further states, “Ongoing professional practice evaluation information is factored into the decision to maintain existing privilege(s), to revise existing privileges, or to revoke an existing privilege prior to or at the time of renewal” (MS.08.01.03).

In the EPs for MS.08.01.03, The Joint Commission says there is a clearly defined process facilitating the evaluation of each practitioner’s professional practice, in which the type of information collected is determined by individual departments and approved by the organized medical staff. Information resulting from the ongoing professional practice evaluation is used to determine whether to continue, limit, or revoke any existing privilege.

**HFAP**

The Healthcare Facilities Accreditation Program (HFAP) has no formal position concerning the delineation of privileges for OPCAB. The bylaws must include the criteria for determining the privileges to be granted to the individual practitioners and the procedure for applying the criteria to individuals requesting privileges (03.01.09). Privileges are granted based on the medical staff’s review of an individual practitioner’s qualifications and its recommendation regarding that individual practitioner to the governing body.

It is also required that the organization have a process to ensure that practitioners granted privileges are working within the scope of those privileges.

Privileges must be granted within the capabilities of the facility. For example, if an organization is not capable of performing open-heart surgery, no physician should be granted that privilege.

In the explanation for standard 03.01.13 related to membership selection criteria, HFAP states, “Basic criteria listed in the bylaws, or the credentials manual, include the items listed in this standard. (Emphasis is placed on training and competence in the requested privileges.)”

The bylaws also define the mechanisms by which the clinical departments, if applicable or the medical staff as a whole establishes criteria for specific privilege delineation.

Periodic appraisals of the suitability for membership and clinical privileges is required to determine whether the individual practitioner’s clinical privileges should be approved, continued, discontinued, revised, or otherwise changed (03.00.04). The appraisals are to be conducted at least every 24 months.
The medical staff is accountable to the governing body for the quality of medical care provided, and quality assessment and performance improvement (03.02.01) information must be used in the process of evaluating and acting on re-privileging and reappointment requests from members and other credentialed staff.

**DNV**

DNV has no formal position concerning the delineation of privileges for OPCAB. MS.12 Standard Requirement (SR) #1 states, “The medical staff bylaws shall include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to those individuals that request privileges.”

The governing body shall ensure that under no circumstances is medical staff membership or professional privileges in the organization dependent solely upon certification, fellowship, or membership in a specialty body or society.

Regarding the Medical Staff Standards related to Clinical Privileges (MS.12), DNV requires specific provisions within the medical staff bylaws for:

- The consideration of automatic suspension of clinical privileges in the following circumstances: revocation/restriction of licensure; revocation, suspension, or probation of a DEA license; failure to maintain professional liability insurance as specified; and noncompliance with written medical record delinquency/deficiency requirements
- Immediate and automatic suspension of clinical privileges due to the termination or revocation of the practitioner’s Medicare/Medicaid status
- Fair hearing and appeal

The Interpretive Guidelines also state that core privileges for general surgery and surgical subspecialties are acceptable as long as the core is properly defined.

DNV also requires a mechanism (outlined in the bylaws) to ensure that all individuals provide services only within the scope of privileges granted (MS.12, SR.4).

Clinical privileges (and appointments or reappointments) are for a period as defined by state law or, if permitted by state law, not to exceed three years (MS.12, SR.2).

Individual practitioner performance data must be measured, utilized, and evaluated as a part of the decision-making for appointment and reappointment. Although not specifically stated, this would apply to the individual practitioner’s respective delineation of privilege requests.

**CRC draft criteria**

The following draft criteria are intended to serve solely as a starting point for the development of an institution’s policy regarding OPCAB.
**Minimum threshold criteria for requesting privileges in OPCAB**

**Basic education:** MD or DO  
**Minimal formal training:** Successful completion of an ACGME- or AOA-approved training program in thoracic or cardiothoracic surgery.  
**Required current experience:** Current demonstrated competence and evidence of the performance of at least 30 OPCAB procedures in the past 12 months to determine competency based on outcomes, or completion of training in the past 12 months.

**References**

If the applicant is recently trained, a letter of reference should come from the director of the applicant’s training program. Alternatively, a letter of reference may come from the applicable department chair and/or clinical service chief at the facility where the applicant most recently practiced.

**Reappointment**

Reappointment should be based on unbiased, objective results of care according to a hospital’s quality assurance mechanism.

Candidates for reappointment should demonstrate current competence and provide evidence of the performance of at least 60 peripheral angiograms in the past 24 months, based on results of ongoing professional practice evaluation or performance monitoring.

In addition, continuing education related to OPCAB should be required.

**For more information**

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