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| BSC2.13 | | Elective Invasive Coronary Angiography (ICA) | |
| Original Policy Date: | August 1, 2020 | Effective Date: | August 1, 2021 |
| Section: | 7.0 Surgery | Page: | Page 1 of 27 |

Policy Statement

This medical policy is **NOT** intended to address ICA for acute coronary syndrome (ACS) or other high-risk situations as addressed in the [Policy Guidelines](#):

- I. Unstable angina or Non-ST-elevation myocardial infarction (NSTEMI)
- II. High Risk for Coronary Artery Disease
- III. Post-Acute Myocardial Infarction
- IV. Other High-Risk Factors

Elective (NOT emergent) Invasive Coronary Angiography (ICA) and catheterization may be considered **medically necessary** when **ALL** of the following are met:

- I. The patient and cardiologist together have reviewed and signed the "[Invasive Coronary Angiography \(ICA\)](#)" decision aid
- II. The patient has completed and signed the "[CollaboRATE](#)" survey
- III. Documentation of **any** of the following:
 - A. The patient is 18 years of age or younger
 - B. Congenital heart disease (CHD)
 - C. Heart failure (HF) (also known as Congestive Heart Failure or CHF)
 - D. Hypertrophic cardiomyopathy (HCM)
 - E. Kawasaki disease (KD) (also known as mucocutaneous lymph node syndrome)
 - F. Post-cardiac transplant in a patient who has not undergone coronary angiography in the previous six months
 - G. Pulmonary artery extrinsic compressions of left main coronary artery
 - H. Valvular heart disease
 - I. Return of angina within 9 months of percutaneous coronary intervention (PCI)
 - J. Canadian Cardiovascular Society (CCS) class I or II classification of angina (see Policy Guidelines section) with intolerance of or failure to respond to optimal medical treatment
 - K. CCS class III or IV classification of angina (with or without a response to optimal medical treatment)

Elective Invasive coronary angiography (ICA) and catheterization for known or suspected coronary artery disease (CAD) is considered **not medically necessary** for all other indications not meeting the medically necessary criteria.

NOTE: Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Emergent catheterization to evaluate or treat an acute coronary syndrome or any of the following are not intended to be subject to review under this medical policy:

Unstable Angina

- **Unstable** angina or non-ST-elevation myocardial infarction (NSTEMI), and intermediate or high risk for adverse outcome, as indicated by **any** of the following:
 - Elevated troponin levels
 - Exertional angina of new onset (even if relieved with rest and requiring a consistent amount of exertion to produce symptoms, angina is considered unstable when it first occurs)
 - Exertional angina that was previously stable and now occurs with less physical exertion
 - Ischemia related heart failure

- Left ventricular ejection fraction (LVEF) less than 40%
- PCI within the past 6 months or coronary artery bypass graft (CABG) within the past 12 months
- An episode of persistent or sustained hemodynamic or ventricular electrical (rhythm) instability
- Recurrent angina for greater than 20 minutes at rest or low activity for greater than 20 minutes despite optimal medical treatment
- New ST segment depression
- Sustained ventricular arrhythmia
- Suspected Prinzmetal's angina (also known as variant angina)

High Risk for Coronary Artery Disease

- Suspected high risk for CAD based on findings from noninvasive testing, as indicated by **any** of the following:
 - Echocardiographic wall motion abnormality involving greater than 2 segments
 - High-risk Duke Treadmill Score (DTS) (less than or equal to -11) (see Policy Guidelines section)
 - Left ventricular ejection fraction (LVEF) of 35% or less at rest
 - Stress electrocardiogram findings of ST-segment elevation, or ventricular arrhythmia, or at least 2 millimeter (mm) of ST-segment depression
 - Stress-induced large perfusion defect (especially if anterior) or multiple moderate size perfusion defects
 - Stress-induced left ventricular dysfunction (exercise LVEF less than 35%)
- Other evidence of high risk on myocardial perfusion imaging, as indicated by **any** of the following:
 - A large fixed perfusion defect with left ventricular dilatation or increased lung uptake of radioisotope
 - A stress-induced moderate perfusion defect with left ventricular dilatation or increased lung uptake of radioisotope
 - Left ventricular enlargement or transient post-stress ischemic left ventricular dilatation

Post-Acute Myocardial Infarction

- Post-acute myocardial infarction (MI), for identifying and predicting high risk when **any** of the following are present:
 - Clinically significant heart failure during hospital course
 - Ischemia provoked by minimal exercise on noninvasive testing
 - Left ventricular ejection fraction (EF) of 45% or less, and patient unable to undergo noninvasive testing

Other High-Risk Factors

- Cardiac risk assessment needed prior to high-risk non-cardiac surgery, for a patient with disability, illness, or physical challenge that prohibits non-invasive testing
- Patient survived sudden cardiac arrest
- Reevaluation of a specific area or structure with the same imaging modality, as indicated by **one or more** of the following:
 - Change in clinical status (e.g., worsening symptoms or new associated symptoms)
 - Need for re-imaging either prior to or after performance of the invasive procedure
 - Need for interval reassessment that may impact the treatment plan
- Suspected acute pericarditis, but signs and symptoms, troponin levels, and pattern of ST elevation cannot definitively rule out acute infarction
- Suspected stent thrombosis, either abrupt closure or subacute, following PCI
- PCI is indicated by Fractional Flow Reserve (FFR) by Coronary Computed Tomographic Angiography (CCTA), but further definition of coronary anatomy is needed prior to PCI

Canadian Cardiovascular Society Angina Grading Scale

The Canadian Cardiovascular Society (CCS) Angina Grading Scale was created by CCS, a national voice for cardiovascular physicians and scientists in Canada. The CCS is a membership organization that represents more than 1,800 professionals in the cardiovascular field. Its mission

is to promote cardiovascular health and care through knowledge translation, professional development and leadership in health policy.¹

Table 1. Canadian Cardiovascular Society Grading of Angina Pectoris

| Grade | Description |
|-----------|---|
| Class I | Ordinary physical activity does not cause angina, such as walking and climbing stairs. Angina with strenuous or rapid or prolonged exertion at work or recreation. |
| Class II | Slight limitation of ordinary activity. Walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, or in cold, or in wind, or under emotional stress, or only during the few hours after awakening. Walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions. |
| Class III | Marked limitation of ordinary physical activity. Walking one or two blocks on the level and climbing one flight of stairs in normal conditions and at normal pace. |
| Class IV | Inability to carry on any physical activity without discomfort – anginal syndrome may be present at rest. |

Campeau Lucien. Grading of angina pectoris.^{2,3}

Available on the Canadian Cardiovascular Society Website at

www.ccs.ca.⁴

Duke Treadmill Score

The Duke Treadmill Score (DTS) is a weighted index combining treadmill exercise time using standard Bruce protocol, maximum net ST segment deviation (depression or elevation), and exercise-induced angina. It was developed to provide accurate diagnostic and prognostic information for the evaluation of patients with suspected coronary heart disease.⁴ The typical observed range of DTS is from -25 (highest risk) to +15 (lowest risk). A low DTS is actually better at excluding ischemic heart disease in women than men. The calculation is done based on the information obtained from an exercise test by this formula:

- $DTS = [Exercise\ duration\ (minutes)] - [5 \times (maximal\ ST\ elevation\ or\ depression)] - [4 \times (treadmill\ angina\ index)]$

Table 2. Duke Treadmill Score⁵

| Duke Treadmill Score Index | | | | | |
|----------------------------|---|--------------------------|--------------------------|------------------|------------------------------------|
| Ex Time | Treadmill exercise time | | | | |
| Max ST | Maximum net ST deviation (except aVR) | | | | |
| Angina Index | Treadmill angina index: 0. No angina during exercise 1. Non-limiting angina 2. Exercise limited angina | | | | |
| DTS | Duke treadmill score | | | | |
| Risk | Low risk | | Score $\geq +5$ | | |
| | Moderate risk | | Score between +4 and -10 | | |
| | High risk | | Score ≤ -11 | | |
| DTS Risk Category | 1-Yr Mortality | No Stenosis $\geq 75\%$ | 1 VD $\geq 75\%$ | 2 VD $\geq 75\%$ | 3 VD $\geq 75\%$ or LM $\geq 75\%$ |
| Men | | | | | |
| Low | 0.9% | 52.6% | 22.4% | 13.6% | 11.4% |
| Mod | 2.9% | 17.8% | 15.6% | 27.9% | 38.7% |
| High | 8.3% | 1.8% | 9.1% | 17.5% | 71.5% |
| Women | | | | | |
| Low | 0.5% | 80.9% | 9.4% | 6.2% | 3.5% |
| Mod | 1.1% | 65.1% | 14.2% | 8.3% | 12.4% |
| High | 1.8% | 10.8% | 18.9% | 24.3% | 46% |
| DTS Risk Category | 5-Yr Mortality | Score | | | |
| Low risk | 3% | Score $\geq +5$ | | | |
| Moderate risk | 10% | Score between +4 and -10 | | | |

| Duke Treadmill Score Index | | |
|----------------------------|-----|------------------|
| High risk | 35% | Score \leq -11 |

aVR: Augmented vector right

VD = Vessel Disease; LM = Left Main

Elective Invasive Coronary Angiography Decision Aid

Use of decision aids can promote shared decision making and may improve patients understanding and enable them to make decisions that are fully informed and consistent with their preferences, values, and goals. A decision aid is a tool used to inform patients about available treatments, along with potential benefits, risks and costs, during clinical encounters. The decision aid is intended for use following the patient pre-operative education course. The resulting decision aid is intended to be nondirective, encouraging clinicians to create a conversation with patients using their own communication styles, while simultaneously ensuring that key information is conveyed and that patient preferences are elicited. Blue Shield of California considers the use of decision aids as a higher level of informed consent and requires patients to acknowledge receipt, review, and sign the Enhanced Clinical Programs (ECP) Elective Invasive Coronary Angiography decision aid as a pre-authorization requirement.

Shared Decision Making

Shared Decision Making (SDM) is a process in which patients openly explore with their physicians' assistance both the available evidence supporting each therapeutic intervention, and also determine what matters most to the patient. This allows both the physician and the patient to reach agreed-upon treatment decisions reflecting mutual goals and expected outcomes. The completion of the CollaboRATE survey and signing of the Elective Invasive Coronary Angiography decision aid by the member helps to assure the member's personal preferences have been considered.

CollaboRATE

Patient-centered health care is a central component of current health policy agendas. CollaboRATE is a 3-Item questionnaire that measures the level of shared decision making in the clinical encounter from the patient's perspective. In the questionnaire, the patient rates, on a scale of 1 to 9, the provider's efforts to understand the surgical plan of care from the patient's perspective. The CollaboRATE SDM tool has demonstrated discriminative validity, concurrent validity, intra-rater reliability, and sensitivity to change.

To access further information, please visit the following websites: <https://www.jmir.org/2014/1/e2/>

Coding:

The following CPT codes may be used for coronary angiography:

- **93454:** Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation;
- **93455:** Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography
- **93456:** Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right heart catheterization
- **93457:** Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography and right heart catheterization
- **93458:** Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and

interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed

- **93459:** Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography
- **93460:** Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed
- **93461:** Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography

Description

Coronary angiography is an invasive procedure that uses a special dye (contrast material) and X-Rays to see how blood flows through the arteries in the heart. Coronary angiography is often done along with cardiac catheterization. This is a procedure which measures pressures in the heart chambers. An area of the body (e.g., the arm or groin) is cleaned and numbed with a local numbing medicine (anesthetic). A thin hollow tube, called a catheter, is passed through an artery and carefully moves it up into the heart. X-ray images help the physician position the catheter. Once the catheter is in place, dye (contrast material) is injected into the catheter. X-ray images are taken to see how the dye moves through the artery. The dye helps highlight any blockages in blood flow. These images are used to detect blockages (coronary artery disease) or spasms of the coronary arteries. Images can help determine whether angioplasty (opening the blockage with a small balloon inserted through the catheters) and stent placement (small, expandable hollow mesh tubes to keep the coronary artery open) is needed or whether coronary artery bypass surgery should be done to get blood past the area of blockage.

Related Policies

- Cardiac Applications of Positron Emission Tomography Scanning
- Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting
- Elective Percutaneous Coronary Intervention (PCI)

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

Invasive coronary angiography interventions (ICA) are surgical procedures, therefore are not regulated by the U.S. Food and Drug Administration (FDA).

Rationale

Background

Coronary angiography is an invasive procedure that includes fluoroscopy after injection of a type of dye that's visible to visualize the great vessels, chambers, and coronary vessels of the heart, as well as venous and arterial bypass grafts or other arterial conduits such as the mammary arteries. The test is generally done to see if there's a restriction in blood flow going to the heart.

Coronary angiography is part of a general group of procedures known as heart (cardiac) catheterizations. Cardiac catheterization procedures can both diagnose and treat heart and blood vessel conditions. A coronary angiogram, which can help diagnose heart conditions, is the most common type of cardiac catheterization procedure.

During a coronary angiogram, a type of dye that's visible by an X-ray machine is injected into the blood vessels of your heart. The X-ray machine rapidly takes a series of images (angiograms), offering a look at your blood vessels. If a blockage is found, a percutaneous coronary intervention (PCI) such as angioplasty may be done to open the blockage. This may be done during the same procedure or at a later time. If there are many blockages or blockages in certain areas, a coronary artery bypass graft (CABG) may be necessary.

Risks of coronary angiography include cardiac tamponade, arrhythmias, injury to a catheterized artery, low blood pressure, allergic reaction to contrast dye, excessive bleeding, kidney damage, stroke or heart attack.

Invasive coronary angiography remains the gold standard for visualization and characterization of the coronary anatomy.

Literature Review

Congenital Heart Disease

Cardiac catheterization for the diagnosis and management of Congenital Heart Disease (CHD) has been increasingly supplemented by noninvasive diagnostic modalities; initially cardiac ultrasound and, more recently, computed tomography (CT) scanning and magnetic resonance imaging (MRI). Advances in these technologies have been logarithmic, and it is likely that in the coming decade both morphologic and functional assessments of this patient population will be increasingly accomplished noninvasively.⁶

Noninvasive methods increasingly limit the need for catheterization unless intervention is considered. Many simple congenital cardiac defects are now sent to surgery without catheterization. Cardiac catheterization and angiocardiology complement these noninvasive techniques in the evaluation of adults with suspected CHD.^{6,7}

Noninvasive imaging is indicated in both children and adults before surgery when repair may involve the coronary arteries or because of chest pain. It may also be indicated for complex congenital heart disease, particularly when intracardiac shunting is present.⁸

The 2008 American College of Cardiology (ACC) and American Heart Association (AHA) Guidelines for adults with CHD suggest the use of diagnostic catheterization primarily to resolve specific issues related to surgical intervention (e.g., preoperative evaluation of coronary arteries, assessment of pulmonary vascular disease and its response to vasoactive agents for planned

surgical intervention, and/or heart or heart/lung transplantation) and as an adjunct to noninvasive assessment of morphologic and/or functional characteristics of complex CHD (e.g., for delineating arterial and venous anatomy in patients with heterotaxy, patients who are candidates for a Fontan procedure, or patients who have had previous palliation in the form of a shunt). The evaluation for possible interventional catheterization is an increasingly common indication for diagnostic catheterization. Catheter intervention, for instance, is commonly sought as the treatment of choice for correcting valvular pulmonary stenosis or regurgitation, branch pulmonary stenosis, residual or recurrent aortic coarctation, and arteriovenous fistulae. Coil or device occlusion of lesions such as patent ductus or secundum ASD is another preferred intervention for treatment.⁷

Cardiac catheterization and coronary angiography may be indicated for accurate measurement of congenital pulmonary or aortic stenosis gradients and to delineate anatomy, as well as for accurate assessment of pulmonary artery (PA) pressure and pulmonary vascular resistance (PVR). Pulmonary angiography and right ventriculography are recommended for pulmonary stenosis in particular. For patients with repaired tetralogy of Fallot, coronary artery compression testing (via cardiac catheterization) is recommended prior to transcatheter valve replacement or right ventricle-to-pulmonary artery conduit stenting. For transposition of the great arteries, the authors note that it is reasonable to perform anatomic evaluation of coronary artery patency in asymptomatic adults following an arterial switch procedure; coronary angiography is recommended if this patency cannot be established noninvasively. Cardiac catheterization can also be useful in the assessment of coarctation and recoarctation of the aorta, of sinus venosus defects and coronary anomalies, and of vascular rings.⁹

Heart Failure or Cardiomyopathy

Coronary angiography is indicated to rule out an ischemic cause of heart failure (HF) or cardiomyopathy (CM), as noninvasive imaging is neither sensitive nor specific in this situation. If not already performed in the hospital, coronary angiography is appropriate for some patients following a myocardial infarction, including those with an ejection fraction of 35% or less, or those who have left ventricular aneurysm.¹⁰

In patients with known CAD and angina or with significant ischemia diagnosed by electrocardiogram (ECG) or noninvasive testing and impaired ventricular function, coronary angiography is indicated. Among those without a prior diagnosis, CAD should be considered as a potential etiology of left ventricular dysfunction (LVD) and should be excluded wherever possible. Coronary angiography may be considered in these circumstances to detect and localize large-vessel coronary obstructions. In patients in whom CAD has been excluded as the cause of LV dysfunction, coronary angiography is generally not indicated unless a change in clinical status suggests interim development of ischemic disease.¹⁰

The American College of Cardiology Foundation, in collaboration with the Society for Cardiovascular Angiography and Interventions and key specialty and subspecialty societies, conducted a review of common clinical scenarios where diagnostic catheterization is frequently considered. The indications (clinical scenarios) were derived from common applications or anticipated uses, as well as from current clinical practice guidelines and results of studies examining the implementation of noninvasive imaging appropriate use criteria. The 166 indications were developed by a diverse writing group and scored by a separate independent technical panel on a scale of 1 to 9, to designate appropriate use (median 7 to 9), uncertain use (median 4 to 6), and inappropriate use (median 1 to 3). Diagnostic catheterization may include several different procedure components. The indications developed focused primarily on 2 aspects of diagnostic catheterization. Many indications focused on the performance of coronary angiography for the detection of coronary artery disease with other procedure components (e.g., hemodynamic measurements, ventriculography) at the discretion of the operator. The majority of the remaining indications focused on hemodynamic measurements to evaluate valvular heart disease, pulmonary hypertension, cardiomyopathy, and other conditions, with the use of coronary angiography at the discretion of the operator. Seventy-five

indications were rated as appropriate, 49 were rated as uncertain, and 42 were rated as inappropriate. The appropriate use criteria for diagnostic catheterization have the potential to impact physician decision making, healthcare delivery, and reimbursement policy. Furthermore, recognition of uncertain clinical scenarios facilitates identification of areas that would benefit from future research.¹¹

The 2012 Canadian Cardiovascular Society Heart Failure (HF) guidelines state that cardiac catheterization and coronary angiography are appropriate for the evaluation of ischemia in heart failure patients.¹²

Coronary angiography is recommended in patients with HF who suffer from angina pectoris recalcitrant to medical therapy, provided the patient is otherwise suitable for coronary revascularization. Coronary angiography is also recommended in patients with a history of symptomatic ventricular arrhythmia or aborted cardiac arrest. Coronary angiography should be considered in patients with HF and intermediate to high pre-test probability of CAD and the presence of ischemia in non-invasive stress tests in order to establish the ischemic etiology and CAD severity.¹³

Hypertrophic Cardiomyopathy

Invasive coronary angiography is indicated in patients with Hypertrophic Cardiomyopathy (HCM) and should be a routine accompaniment to an invasive catheterization performed in a patient with HCM for assessment of hemodynamic status and in such cases, should generally be performed after documentation of hemodynamics so as not to influence important measurements such as the magnitude of the LVOT gradient. When catheterization is performed, invasive coronary angiography should be undertaken before alcohol septal ablation in order to define the anatomy of the septal perforators in detail and exclude obstructive coronary stenoses. Furthermore, if alcohol septal ablation is being considered, the decision may be influenced by the location and extent of coronary disease as defined by coronary angiography.¹⁴

Kawasaki Disease

Kawasaki disease (KD) is associated with coronary artery aneurysms, for which coronary angiography is useful for definitive imaging of the coronary arteries and great vessels. The standard for coronary artery assessment, particularly in the adult patient, is invasive angiography. It provides a detailed image of the coronary artery lumen and is very useful in defining regional flow-limiting stenoses and assessing them for potential intervention. Fractional flow reserve, measured during angiography, is a common method for determining the ischemia-causing potential of atherosclerotic stenoses. Discrete coronary artery stenosis in KD can also be assessed, with similar cut points as in adults with atherosclerosis. An additional insight from fractional flow reserve (FFR) in KD relates to the impact of coronary artery aneurysms on the arterial pressure. Turbulence-related pressure loss at dilated segments may create a drop in pressure along the artery, but FFR assessed in a small series of KD-associated aneurysms documented pressure drops that were smaller than threshold values used to predict pathophysiological importance. Patients with evidence of inducible myocardial ischemia on testing should undergo invasive coronary angiography. Although invasive coronary angiography is rarely performed during the acute phase of Kawasaki disease, angiography can be useful for later identification and periodic surveillance of coronary artery aneurysms, particularly when signs of ischemia are present. The adult with a known remote history of KD presenting with ST-elevation myocardial infarction (STEMI) should be referred for emergency coronary angiography and determination of the best mode of revascularization. Unlike the patient in the acute/subacute phase of KD presenting with STEMI, the adult presenting with STEMI may have typical atherosclerotic disease as the cause of their STEMI, and standard percutaneous coronary intervention (PCI) techniques may be appropriate. If the patient is found to have an acutely thrombosed aneurysm, then a judgment decision will need to be made by the interventional cardiologist as to whether PCI should be attempted or a pharmacological strategy should be used.¹⁵

Post-Cardiac Transplant

Coronary angiography coupled with assessment of cardiac allograft function maintains the highest level of evidence and consensus opinion for inclusion in the final nomenclature. The advantages of angiography are that it is universal in availability for both adult and pediatric patients, clinically accepted, and applicable at any time in the post-transplantation process (favorable for longitudinal and snap-shot assessments).¹⁶

There are distinct difficulties with the performance of invasive tests in children. In experienced hands, coronary angiography, including selective ostial injection, is technically feasible with a low complication rate. The highest risk is in the infant population, generally considered to have a weight of less than 10 kg. Femoral arterial thrombus formation is a risk, especially in smaller patients. Many pediatric centers perform coronary angiography under a general anesthetic in a significant proportion of their pediatric transplant patients. Technical expertise and facilities exist in all pediatric heart transplant centers.¹⁶

It has been noted that a major cause of death in post-transplant patients is coronary artery vasculopathy, and cardiac catheterization with intravascular ultrasound is useful for surveillance of cardiac allograft vasculopathy (CAV) and silent obstructive coronary artery disease.^{17,18} Right heart catheterization is useful for hemodynamic assessment in post-transplant patients and to facilitate endomyocardial biopsy to provide histologic monitoring for transplant rejection.¹⁸

Pulmonary Artery Extrinsic Compression

Coronary angiography has limitations in evaluating left main coronary artery (LMCA) stenosis. Intracoronary imaging techniques such as intravascular ultrasound (IVUS) can provide critical information in this scenario. An IVUS minimal lumen area of 6 mm² is a safe cutoff value for deferring revascularization in LMCA disease. Furthermore, the lack of correlation between coronary angiography and IVUS measurements is well known. In the LITRO (studio de Lesiones Intermedias de TRonco) study, 43% of patients with angiographic stenosis >50% showed a minimal lumen area >6 mm².¹⁹ This cutoff value also predicts the physiological significance of LMCA stenosis assessed by fractional flow reserve. The correlation between CA and IVUS is even poorer in ostial LMCA stenosis. The role of IVUS in LMCA external compression could be particularly important due to the limited value of noninvasive ischemia detection techniques in identifying candidates to revascularization. Therefore, coronary angiography could be insufficient to clarify the severity and/or functional implications of the LMCA stenosis in this clinical setting. This could lead to unnecessary interventions with subsequently higher rates of complications. The authors report a prevalence of significant LMCA compression by an enlarged pulmonary artery of 6% in the overall PAH population. However, this finding has been described also in asymptomatic patients who are at risk of developing ventricular arrhythmias and sudden death. Therefore, screening programs should target all PAH patients independently of the clinical status to avoid LMCA compression overlooking.²⁰

Valvular Heart Disease

Coronary angiography is indicated before valve intervention **in patients with symptoms of angina, objective evidence of ischemia, decreased Left Ventricular (LV) systolic function, history of CAD, or coronary risk factors (including men age >40 years and postmenopausal women).** Coronary angiography can be avoided in young patients (men <40 years of age and premenopausal women) with no atherosclerotic risk factors and in patients in whom the risks outweigh the benefits, such as in patients with acute aortic dissection, large aortic valve vegetation, or occlusive prosthetic thrombosis.²¹

Coronary angiography should be performed as part of the evaluation of patients with chronic severe secondary Mitral Regurgitation (MR). Surgery without coronary angiography is reasonable for patients having emergency valve surgery for acute valve regurgitation, disease of the aortic sinuses or ascending aorta, or infective endocarditis (IE).²¹

Cardiac catheterization may be indicated to assess hemodynamics, coronary artery anatomy, and severity of valve disease in the setting of equivocal echocardiographic evidence regarding the severity of valvular heart disease.²¹

Coronary Artery Disease

Duke Treadmill Score

Exercise testing is useful in the assessment of symptomatic patients for diagnosis of significant or extensive coronary disease and to predict their future risk of cardiac events. The Duke treadmill score (DTS) is a composite index that was designed to provide survival estimates based on results from the exercise test, including ST-segment depression, chest pain, and exercise duration. However, its usefulness for providing diagnostic estimates has yet to be determined.²²

Mark et al (1987) evaluated 2842 consecutive patients with chest pain (CP) who had both treadmill testing cardiac catheterization. The population was randomly divided into two equal-sized groups and the Cox regression model was used in one to form a treadmill score that was then validated in the other group. The final treadmill score was calculated as follows: exercise time--(5 X ST deviation)--(4 X treadmill angina index). Using this treadmill score, 13% of the patients were found to be at high risk; 53%, at moderate risk; and 34%, at low risk. The treadmill score added independent prognostic information to that provided by clinical data, coronary anatomy, and left ventricular ejection fraction: patients with three-vessel disease with a score of -11 or less had a 5-year survival rate of 67%, and those with a score of +7 or more had a 5-year survival rate of 93%. The treadmill score was useful for stratifying prognosis in patients with suspected coronary artery disease who were referred for catheterization, and may provide a useful adjunct to clinical decision making in the larger population of patients being evaluated for chest pain.²³

Coronary angiography is designed to provide detailed information about the size and distribution of coronary vessels, the location and extent of atherosclerotic obstruction, and the suitability for revascularization. The LV angiogram, usually performed with coronary angiography, provides an assessment of the extent of focal and global LV dysfunction and of the presence and severity of coexisting disorders (e.g., valvular or other associated lesions). Patients with non-ST-elevation acute coronary syndrome (NSTEMI-ACS) can be divided into risk groups on the basis of their initial clinical presentation.^{24,25}

Risk stratification identifies patients who are most likely to benefit from subsequent revascularization. Patients with left main disease or multivessel CAD with reduced LV function are at high risk for adverse outcomes and are likely to benefit from CABG. Clinical evaluation and noninvasive testing aid in the identification of most patients at high risk because they often have ≥ 1 of the following high-risk features: advanced age (>70 years of age), prior MI, revascularization, ST deviation, HF, depressed resting LV function (i.e., LVEF ≤ 0.40) on noninvasive study, or noninvasive stress test findings, including magnetic resonance imaging.²⁶ Any of these risk factors or diabetes mellitus may aid in the identification of high-risk patients who could benefit from an invasive strategy.²⁴

Some patients with NSTEMI-ACS are not in the very high-risk group and do not have findings that portend a high risk for adverse outcomes. They are not likely to receive the same degree of benefit from routine revascularization afforded to high-risk patients, and an invasive study is optional for those at lower risk and can be safely deferred pending further clinical evidence. Decisions about coronary angiography in patients who are not at high risk according to findings on clinical examination and noninvasive testing can be individualized on the basis of patient preferences and/or symptoms.²⁴

In contrast to noninvasive tests, coronary angiography provides detailed structural information for assessment of prognosis and appropriate management. When combined with LV angiography, it also provides an assessment of global and regional LV function. Coronary angiography is usually indicated in patients with NSTEMI-ACS who have recurrent symptoms or

ischemia despite adequate medical therapy or who are at high risk as categorized by clinical findings (HF, serious ventricular arrhythmias), noninvasive test findings (significant LV dysfunction with EF <0.40, large anterior or multiple perfusion defects or wall motion abnormalities on echocardiography, high-risk Duke treadmill score ≤ -11), high-risk TIMI or GRACE scores, or markedly elevated troponin levels. Patients with NSTEMI-ACS who have had previous PCI or CABG should also be considered for early coronary angiography, unless prior coronary angiography data indicate that no further revascularization is feasible.²⁴

The general indications for coronary angiography and revascularization should be tempered by individual patient characteristics and preferences (a patient-centered approach). Patient and clinician judgments about risks and benefits are important for patients who might not be candidates for coronary revascularization, such as very frail older adults and those with serious comorbid conditions (e.g., severe hepatic, pulmonary, or renal failure; active or inoperable cancer).²⁴

According to Deharo et al (2017), in patients with non-ST-segment-elevation myocardial infarction (NSTEMI) and GRACE (Global Registry of Acute Coronary Events) score >140, coronary angiography (CAG) is recommended by European and American guidelines within 24 hours. The trial's objective was to study the association of very early (i.e., ≤ 12 hours), early (12-24 hours), and delayed (>24 hours) CAG in patients with NSTEMI with GRACE score >140 with ischemic outcomes. The TAO trial (Treatment of Acute Coronary Syndrome With Otamixaban) randomized patients with NSTEMI and CAG scheduled within 72 hours to heparin plus eptifibatid versus otamixaban. In this post hoc analysis, patients with a GRACE score >140 were categorized into 3 groups according to timing of CAG from admission (<12, ≥ 12 -<24, and ≥ 24 hours). The primary ischemic outcome was the composite of all-cause death and myocardial infarction within 180 days of randomization. CAG was performed in 4071 patients (<12 hours, n=1648 [40.5%]; 12-24 hours, n=1420 [34.9%]; ≥ 24 hours, n=1003 [24.6%]). With CAG ≥ 24 hours as a reference, CAG from 12 to 24 hours was not associated with a lower risk of primary ischemic outcome at 180 days (odds ratio, 0.96; 95% confidence interval, 0.75-1.23), whereas CAG <12 hours was associated with a lower risk of death and myocardial infarction (odds ratio, 0.71; 95% confidence interval, 0.55-0.91). Performing CAG <12 hours was also associated with a lower risk of death and myocardial infarction (odds ratio, 0.76; 95% confidence interval, 0.61-0.94; P=0.01) compared with CAG performed at 12 to 24 hours. No difference was observed in bleeding complications. The study showed that in patients with high-risk NSTEMI, undergoing CAG within the initial 12 hours after admission (as opposed to later, either 12-24 or ≥ 24 hours) was associated with lower risk of ischemic outcomes at 180 days.²⁷

Early Invasive and Ischemia-Guided Strategies: Recommendations²⁴

Class I

1. An urgent/immediate invasive strategy (diagnostic angiography with intent to perform revascularization if appropriate based on coronary anatomy) is indicated in patients (men and women) with NSTEMI-ACS who have refractory angina or hemodynamic or electrical instability (without serious comorbidities or contraindications to such procedures).^{28,29,30,31} (Level of Evidence: A)
2. An early invasive strategy (diagnostic angiography with intent to perform revascularization if appropriate based on coronary anatomy) is indicated in initially stabilized patients with NSTEMI-ACS (without serious comorbidities or contraindications to such procedures) who have an elevated risk for clinical events (see Table 1).^{28,29,30,31,32,33,38} (Level of Evidence: B)

Class IIa

1. It is reasonable to choose an early invasive strategy (within 24 hours of admission) over a delayed invasive strategy (within 25 to 72 hours) for initially stabilized high-risk patients with NSTEMI-ACS. For those not at high/intermediate risk, a delayed invasive approach is reasonable.³⁴ (Level of Evidence: B)

Class IIb

1. In initially stabilized patients, an ischemia-guided strategy may be considered for patients with NSTEMI-ACS (without serious comorbidities or contraindications to this approach) who have an elevated risk for clinical events.^{31,32} (Level of Evidence: B)
2. The decision to implement an ischemia-guided strategy in initially stabilized patients (without serious comorbidities or contraindications to this approach) may be reasonable after considering clinician and patient preference. (Level of Evidence: C)

Class III: No Benefit

1. An early invasive strategy (i.e., diagnostic angiography with intent to perform revascularization) is not recommended in patients with:
 - a. Extensive comorbidities (e.g., hepatic, renal, pulmonary failure; cancer), in whom the risks of revascularization and comorbid conditions are likely to outweigh the benefits of revascularization. (Level of Evidence: C)
 - b. Acute chest pain and a low likelihood of ACS who are troponin-negative (Level of Evidence: C), especially women.³⁵ (Level of Evidence: B)

| Table 1. Factors Associated with Appropriate Selection of Early Invasive Strategy or Ischemia-Guided Strategy in Patients with NSTEMI-ACS | |
|---|--|
| Immediate invasive (within 2 hr.) | <ul style="list-style-type: none"> • Refractory angina • Signs or symptoms of HF or new or worsening mitral regurgitation • Hemodynamic instability • Recurrent angina or ischemia at rest or with low-level activities despite intensive medical therapy • Sustained VT or VF |
| Ischemia-guided strategy | <ul style="list-style-type: none"> • Low-risk score (e.g., TIMI [0 or 1], GRACE [<109]) • Low-risk Tn-negative female patients • Patient or clinician preference in the absence of high-risk features |
| Early invasive (within 24 hr.) | <ul style="list-style-type: none"> • None of the above, but GRACE risk score >140 • Temporal change in Tn • New or presumably new ST depression |
| Delayed invasive (within 25–72 hr.) | <ul style="list-style-type: none"> • None of the above but diabetes mellitus • Renal insufficiency (GFR <60 mL/min/1.73 m²) • Reduced LV systolic function (EF <0.40) • Early postinfarction angina • PCI within 6 mo. • Prior CABG • GRACE risk score 109–140; TIMI score ≥ 2 |

CABG indicates coronary artery bypass graft; EF, ejection fraction; GFR, glomerular filtration rate; GRACE, Global Registry of Acute Coronary Events²⁹; HF, heart failure; LV, left ventricular; NSTEMI-ACS, non-ST-elevation acute coronary syndrome; PCI, percutaneous coronary intervention; TIMI, Thrombolysis In Myocardial Infarction²⁸; Tn, troponin; VF, ventricular fibrillation; and VT, ventricular tachycardia.

Several studies and meta-analyses have concluded that a strategy of routine invasive therapy is generally superior to an ischemia-guided strategy or selectively invasive approach.^{35,36} One study reported that the routine invasive strategy resulted in an 18% relative reduction in death or MI, including a significant reduction in MI alone.³⁷ The routine invasive arm was associated with

higher in-hospital mortality (1.8% versus 1.1%), but this disadvantage was more than compensated for by a significant reduction in mortality between discharge and the end of follow-up (3.8% versus 4.9%). The invasive strategy was also associated with less angina and fewer rehospitalizations. Patients undergoing routine invasive treatment also had improved quality of life. In an analysis of individual patient data³⁶ (Fox KA et al. 2010) that reported 5-year outcomes from the FRISC (Framingham and Fast Revascularization During Instability in Coronary Artery Disease)-II trial³⁸, ICTUS (Invasive Versus Conservative Treatment in Unstable Coronary Syndromes) trial³¹, and RITA (Randomized Trial of a Conservative Treatment Strategy Versus an Interventional Treatment Strategy in Patients with Unstable Angina)-3 trial³³, 14.7% of patients (389 of 2721) randomized to a routine invasive strategy experienced cardiovascular death or nonfatal MI versus 17.9% of patients (475 of 2746) in the selective invasive strategy (HR: 0.81; 95% CI: 0.71 to 0.93; $P=0.002$). The most marked treatment effect was on MI (10.0% routine invasive strategy versus 12.9% selective invasive strategy), and there were consistent trends for fewer cardiovascular deaths (HR: 0.83; 95% CI: 0.68 to 1.01; $P=0.068$) and all-cause mortality (HR: 0.90; 95% CI: 0.77 to 1.05). There were absolute reductions of 2.0% to 3.8% in cardiovascular death or MI in the low- and intermediate-risk groups and an 11.1% absolute risk reduction in the highest-risk patients. The invasive strategy demonstrated its greatest advantage in the highest-risk stratum of patients with no significant benefit on mortality over the noninvasive approach in moderate- and low-risk patients.³⁹ An ischemia-guided strategy has been used with favorable results in initially stabilized patients with NSTEMI-ACS at elevated risk for clinical events, including those with positive troponin levels.³¹ One limitation of these studies is the absence of adherence to optimal medical therapy in non-invasively treated patients during long-term management. In addition, in FRISC-II, invasive management was delayed and patients with markedly positive stress tests (up to 2.9-mm exercise-induced ST depression) were randomized to noninvasive or invasive therapy.²⁴

Maddox et al (2014) published a retrospective cohort study of all US veterans undergoing elective coronary angiography for CAD between October 2007 and September 2012 in the Veterans Affairs health care system. Patients with prior CAD events were excluded. Among 37,674 patients, 8384 patients (22.3%) had nonobstructive CAD and 20,899 patients (55.4%) had obstructive CAD. Within 1 year, 845 patients died and 385 were rehospitalized for MI. Among patients with no apparent CAD, the 1-year MI rate was 0.11% ($n = 8$, 95% CI, 0.10%-0.20%) and increased progressively by 1-vessel nonobstructive CAD, 0.24% ($n = 10$, 95% CI, 0.10%-0.40%); 2-vessel nonobstructive CAD, 0.56% ($n = 13$, 95% CI, 0.30%-1.00%); 3-vessel nonobstructive CAD, 0.59% ($n = 6$, 95% CI, 0.30%-1.30%); 1-vessel obstructive CAD, 1.18% ($n = 101$, 95% CI, 1.00%-1.40%); 2-vessel obstructive CAD, 2.18% ($n = 110$, 95% CI, 1.80%-2.60%); and 3-vessel or LM obstructive CAD, 2.47% ($n = 137$, 95% CI, 2.10%-2.90%). After adjustment, 1-year MI rates increased with increasing CAD extent. Relative to patients with no apparent CAD, patients with 1-vessel nonobstructive CAD had a hazard ratio (HR) for 1-year MI of 2.0 (95% CI, 0.8-5.1); 2-vessel nonobstructive HR, 4.6 (95% CI, 2.0-10.5); 3-vessel nonobstructive HR, 4.5 (95% CI, 1.6-12.5); 1-vessel obstructive HR, 9.0 (95% CI, 4.2-19.0); 2-vessel obstructive HR, 16.5 (95% CI, 8.1-33.7); and 3-vessel or LM obstructive HR, 19.5 (95% CI, 9.9-38.2). One-year mortality rates were associated with increasing CAD extent, ranging from 1.38% among patients without apparent CAD to 4.30% with 3-vessel or LM obstructive CAD. After risk adjustment, there was no significant association between 1- or 2-vessel nonobstructive CAD and mortality, but there were significant associations with mortality for 3-vessel nonobstructive CAD (HR, 1.6; 95% CI, 1.1-2.5), 1-vessel obstructive CAD (HR, 1.9; 95% CI, 1.4-2.6), 2-vessel obstructive CAD (HR, 2.8; 95% CI, 2.1-3.7), and 3-vessel or LM obstructive CAD (HR, 3.4; 95% CI, 2.6-4.4). Similar associations were noted with the combined outcome. The patients undergoing elective coronary angiography, nonobstructive CAD, compared with no apparent CAD, was associated with a significantly greater 1-year risk of MI and all-cause mortality. These findings suggest clinical importance of nonobstructive CAD and warrant further investigation of interventions to improve outcomes among these patients.⁴⁰

Larson et al (2012) published a systematic review and meta-analysis to address the question: "In patients with return of spontaneous circulation following out-of-hospital cardiac arrest, does acute coronary angiography with coronary intervention improve survival compared to

conventional treatment?" Thirty-two non-randomized studies were included of which 22 were case-series without patients with conservative treatment. Seven studies with specific efforts to control confounding had statistical evidence to support the use of acute coronary angiography following resuscitation from out-of-hospital cardiac arrest. The remaining 25 studies were considered neutral. Following acute coronary angiography, the survival to hospital discharge, 30 days or six months ranged from 23% to 86%. In patients without an obvious non-cardiac etiology, the prevalence of significant coronary artery disease ranged from 59% to 71%. Electrocardiographic findings were unreliable for identifying angiographic findings of acute coronary syndrome. Ten comparison studies demonstrated a pooled unadjusted odds ratio for survival of 2.78 (1.89; 4.10) favoring acute coronary angiography. The authors of this review came to the conclusion that there are no randomized studies that exist on acute coronary angiography following out-of-hospital cardiac arrest. An increasing number of observational studies support feasibility and a possible survival benefit of an early invasive approach. In patients without an obvious non-cardiac etiology, acute coronary angiography should be strongly considered irrespective of electrocardiographic findings due to a high prevalence of coronary artery disease.⁴¹

Acute coronary thrombotic occlusion is the most common trigger of cardiac arrest leading Zanuttini et al (2012) to assess the impact of an invasive strategy characterized by emergency coronary angiography and subsequent percutaneous coronary intervention (PCI), if indicated, on in-hospital survival of resuscitated patients with out-of-hospital cardiac arrest (OHCA) and no obvious extracardiac cause who do not regain consciousness soon after recovery of spontaneous circulation. Ninety-three consecutive patients (67 ± 12 years old, 76% men) were included in the study. Clinical characteristics and coronary angiographic and in-hospital outcome data were retrospectively collected. Multivariate Cox proportional-hazards analysis was performed to identify independent determinants of in-hospital survival. Coronary angiography was performed in 66 patients (71%). Forty-eight patients underwent emergency coronary angiography; in the remaining 18 patients, mean time from OHCA to coronary angiography was 13 ± 10 days. In patients referred to emergency coronary angiography, successful emergency PCI of a culprit coronary lesion was performed in 25 patients (52%). In-hospital survival rate was 54%. At multivariate analysis, emergency coronary angiography (hazard ratio 2.32, 95% confidence interval 1.23 to 4.38, $p = 0.009$) and successful emergency PCI (hazard ratio 2.54, 95% confidence interval 1.35 to 4.8, $p = 0.004$) were independently related to in-hospital survival in the overall study population; delay in performing coronary angiography (hazard ratio 0.95, 95% confidence interval 0.92 to 0.99, $p = 0.013$) was independently related to in-hospital mortality in patients referred to coronary angiography. In conclusion, an invasive strategy characterized by emergency coronary angiography and subsequent PCI, if indicated, seems to improve in-hospital outcome of resuscitated but unconscious patients with OHCA without obvious extracardiac cause.⁴²

Lee et al (2018) reported that the applicability of Synergy Between Percutaneous Coronary Intervention With Taxus and Cardiac Surgery (SYNTAX) scores to left main coronary artery disease (CAD) has been questioned. A simplified alternative is needed for guiding decision making; therefore the authors evaluated the prognostic value of a simplified angiographic classification in comparison with a Synergy Between Percutaneous Coronary Intervention With Taxus and Cardiac Surgery score-based approach for patients with left main CAD undergoing drug-eluting stent implantation. The proposed approach classified left main CAD as either extensive ($n=819$), defined as left main bifurcation lesions with an involvement of ostial left circumflex artery or as any left main lesion plus multivessel CAD, or limited ($n=453$), defined as ostial/midshaft lesions or left main bifurcation lesions without an involvement of ostium of left circumflex artery, alone or plus 1-vessel disease. The databases from 4 prospective Premier of Randomized Comparison of Bypass Surgery versus Angioplasty Using Sirolimus-Eluting Stent in Patients with Left Main Coronary Artery Disease studies were pooled, and the primary outcome was a major adverse cardiac event, defined as death, myocardial infarction, or repeat revascularization. During follow-up (median 38 months; interquartile range, 36-61 months), the risk for major adverse cardiac event was significantly higher with extensive than with limited left main CAD (adjusted hazard ratio,

2.13; 95% confidence interval, 1.54-2.94; $P < 0.001$). The risk for a composite outcome of death or myocardial infarction was also higher with extensive left main CAD (adjusted hazard ratio, 1.75; 95% confidence interval, 1.08-2.85; $P = 0.02$). However, Synergy Between Percutaneous Coronary Intervention With Taxus and Cardiac Surgery score tertiles did not effectively stratify these 2 outcome measures. Compared with Synergy Between Percutaneous Coronary Intervention With Taxus and Cardiac Surgery scores, the simpler angiographic approach provided better discrimination for future cardiovascular events in patients with left main CAD undergoing drug-eluting stent implantation.⁴³

Revascularization in stable ischemic heart disease (SIHD) is indicated in patients on optimal medical therapy with angina and/or demonstrable ischemia and a significant stenosis in one or more epicardial coronary arteries. Angiography alone, however, cannot accurately determine the hemodynamic significance of coronary lesions, particularly those of intermediate stenosis severity. A lesion may appear significant on coronary angiogram but may not have functional significance. Percutaneous coronary intervention (PCI) of functionally insignificant coronary artery lesions may have serious consequences; therefore, judicious decision-making in the cardiac catheterization laboratory is indicated. For this reason, it is becoming increasingly important to show that a stenosis is capable to induce myocardial ischemia prior to intervention. Fractional flow reserve (FFR) has emerged as a useful tool for this purpose.⁴⁴

Shared Decision Making (SDM)

Shared decision making (SDM) is promoted as an ideal model to incorporate in the treatment plan between patient and physician. This is based on the premise that the best medical decision for an individual patient incorporates the patient's preferences and values through the process of information sharing and planning. This idea involves at least two participants—the clinician and the patient.⁴⁵⁻⁵⁰ It represents the optimal physician-patient communication. Patients most likely to perceive their physicians as providing excellent care are those experiencing their preferred decision-making style with their primary physicians.^{51,52} Studies show that patient satisfaction, medication compliance, and health outcomes are improved by shared decision making.⁵³⁻⁵⁵

On July 19, 2015, the first joint International Shared Decision-Making/International Society for Evidence-Based Health Care (ISDM/ISEHC) Conference met in Sydney, Australia with over 300 people from around the globe to share knowledge and inspire action to improve the entire health care experience. Highlights of this meeting included:

- “Informed consent” is gaining importance connected with the use of the SDM, which includes a collaborative conversation around the patient's informed preferences and the best available scientific evidence.
- Aligned incentives are necessary to maximize SDM, but not necessarily monetary incentives.
- Increasing in interest and gaining support is the inclusion of family engagement in the decision-making process with the patient/family/care team (called a triad) rather than the patient/care team (called a dyad). The discussion was how to make this a reality, as it has long been felt the family needed to be part of the SDM, but not easily implemented.
- Development of learning programs/greater communication skills for medical students was repeatedly discussed, looking for ways to include training for these as learned skills to build conversations around patient preferences and evidence-based scientific medicine/practice.⁵⁶

Use of decision aids can promote shared decision making, and may improve patients understanding and enable them to make decisions that are fully informed and consistent with their preferences, values and goals. Development of a decision aid (Blue Shield of California “Elective Invasive Coronary Angiography (ICA)” decision aid) to promote shared decision making between clinicians and patients regarding the choice of ICA+ optimal medical therapy (OMT) vs. OMT for treatment of stable CAD. The selection of ICA+OMT vs. OMT alone for stable CAD represents a preference-sensitive decision where comparable, alternative treatments exist.

The decision aid is intended for use following stress testing and upstream from diagnostic angiography; if diagnostic angiography is performed, the minority of patients in whom a choice of surgery is then relevant would no longer utilize the decision aid. The resulting decision aid is intended to be nondirective, encouraging clinicians to create a conversation with patients using their own communication styles, while simultaneously ensuring that key information is conveyed and that patient preferences are elicited.^{57,58}

Optimal antianginal medical therapy is defined as the use of at least 2 classes of therapies to reduce anginal symptoms. ACC/AHA guidelines suggest that beta-blockers should be considered as initial therapy for chronic stable angina. Current practice guidelines indicate low-risk patients with chronic stable angina should be treated initially with optimal medical therapy (OMT) and lifestyle modification.⁵⁹⁻⁶⁴

Current guidelines for the management of stable angina emphasize risk factor modification, namely smoking cessation, exercise, diabetes mellitus management, lipid lowering, antianginal, and antihypertensive therapies. Despite the best efforts of the clinician, all patients may not achieve target goals for risk factor modification. However, a plan of care to address risk factors is assumed to be occurring in patients represented in the indications.⁶⁴

Hospitals and clinicians are encouraged to contribute ICA data to a national Cardiovascular Data Registry (The NCDR CathPCI Registry).

CollaboRATE

Patient-centered health care is a central component of current health policy agendas. Shared decision making (SDM) is considered to be the pinnacle of patient engagement and methods to promote this are becoming commonplace. However, the measurement of SDM continues to prove challenging. Reviews have highlighted the need for a patient-reported measure of SDM that is practical, valid, and reliable to assist implementation efforts. In consultation with patients, CollaboRATE was developed, a 3-item measure of the SDM process. Barr et al (2014) completed a study identifying the need for scalable patient-reported measure of the SDM process. In the current project, the study assessed the psychometric properties of CollaboRATE. A representative sample of the US population was recruited online and was randomly allocated to view 1 of 6 simulated doctor-patient encounters in January 2013. Three dimensions of SDM were manipulated in the encounters: (1) explanation of the health issue, (2) elicitation of patient preferences, and (3) integration of patient preferences. Participants then completed CollaboRATE (possible scores 0-100) in addition to 2 other patient-reported measures of SDM: the 9-item Shared Decision Making Questionnaire (SDM-Q-9) and the Doctor Facilitation subscale of the Patient's Perceived Involvement in Care Scale (PICS). A subsample of participants was resurveyed between 7 and 14 days after the initial survey. This study assessed CollaboRATE's discriminative, concurrent, and divergent validity, intrarater reliability, and sensitivity to change. The final sample consisted of 1341 participants. CollaboRATE demonstrated discriminative validity, with a significant increase in CollaboRATE score as the number of core dimensions of SDM increased from zero (mean score: 46.0, 95% CI: 42.4-49.6) to 3 (mean score 85.8, 95% CI: 83.2-88.4). CollaboRATE also demonstrated concurrent validity with other measures of SDM, excellent intrarater reliability, and sensitivity to change; however, divergent validity was not demonstrated. The fast and frugal nature of CollaboRATE lends itself to routine clinical use. Further assessment of CollaboRATE in real-world settings is required.⁴⁸

Elwyn et al (2013) completed a study with an objective of measuring the process of shared decision making is a challenge, which constitutes a barrier to research and implementation. The aim of the study was to report the development of CollaboRATE, brief patient-reported measure of shared decision making. The following stages were utilized: (1) item formulation; (2) cognitive interviews; (3) item refinement; and (4) pilot testing of final items. Participants were over 18 years old and recruited from the public areas of the Dartmouth-Hitchcock Medical Center. The key finding of this study is that developing a brief patient-reported measure of shared decision making requires a move away from terms such as 'decisions', 'options' and 'preferences'.

Although technically correct, these terms act as barriers. They are often unfamiliar, and they also implicitly assume that patients are willing to take active roles in decision making; whereas patients are often unaware that decisions are required, or have taken place, never mind feel that they could or should have participated in them. The outcome of this study concluded that these methods have allowed the development of a brief, patient-reported measure of shared decision making that is highly accessible to intended users.⁶⁵

The principles of shared decision making are well documented but there is a lack of guidance about how to accomplish the approach in routine clinical practice. The aim is to translate existing conceptual descriptions into a three-step model that is practical, easy to remember, and can act as a guide to skill development. Achieving shared decision making depends on building a good relationship in the clinical encounter so that information is shared and patients are supported to deliberate and express their preferences and views during the decision making process. To accomplish these tasks, a model was proposed of how to do shared decision making that is based on choice, option and decision talk. The model has three steps: a) introducing choice, b) describing options, often by integrating the use of patient decision support, and c) helping patients explore preferences and make decisions. This model rests on supporting a process of deliberation, and on understanding that decisions should be influenced by exploring and respecting “what matters most” to patients as individuals, and that this exploration in turn depends on them developing informed preferences.⁶⁶

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
 - Angina class (Canadian Cardiovascular Society Grading of Angina Pectoris, Class I, II, III or IV)
 - Unusual location of obstruction(s), unusual coronary anatomy, or unusual flow dynamics noted by the cardiologist if applicable
 - Intercurrent cardiac disease (e.g., congenital heart disease, congestive heart failure, hypertrophic cardiomyopathy, kawasaki disease, post-cardiac transplant, myocardial disease, arrhythmia, valvular disease) if applicable
 - Current or recent smoking history (within one year)
 - Cardiologist documentation of difficult-to-control uncontrolled hypertension on maximal therapy or uncontrolled dyslipidemia on maximal therapy if applicable
 - Diabetes mellitus with a first or second degree relative with premature coronary artery disease (i.e., age less than 65, MI or coronary intervention) if applicable
 - Strong family history of coronary artery disease if applicable
 - Prior PCI or CABG procedure if applicable
- Pertinent past procedural and surgical history
- Radiology report(s) (i.e., MRI, FFRct, CCTA)
- Completed and signed Blue Shield of California ICA Decision Aid by the cardiologist and patient
- Completed and signed CollaboRATE survey by the patient

Post Service (in addition to the above, please include the following):

- Results/reports of tests performed
- Procedure report(s)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

| Type | Code | Description |
|------|-------|---|
| CPT® | 93454 | Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation |
| | 93455 | Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography |
| | 93456 | Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right heart catheterization |
| | 93457 | Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography and right heart catheterization |
| | 93458 | Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed |
| | 93459 | Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography |
| | 93460 | Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed |
| | 93461 | Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, |

| Type | Code | Description |
|-------|------|---|
| | | imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography |
| HCPCS | None | |

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

| Effective Date | Action |
|----------------|---|
| 08/01/2020 | New policy |
| 08/01/2021 | Annual review. No change to policy statement. |

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well

BSC2.13 Elective Invasive Coronary Angiography (ICA)

Page 24 of 27

as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

| POLICY STATEMENT (No changes) | |
|--|---|
| BEFORE | AFTER |
| <p>Elective Invasive Coronary Angiography (ICA) BSC2.13</p> <p>Policy Statement: This medical policy is NOT intended to address ICA for acute coronary syndrome (ACS) or other high-risk situations as addressed in the Policy Guidelines:</p> <ul style="list-style-type: none"> • <i>Unstable</i> angina or Non-ST-elevation myocardial infarction (NSTEMI) • High Risk for Coronary Artery Disease • Post-Acute Myocardial Infarction • Other High-Risk Factors <p>Policy Statement: Elective (NOT emergent) Invasive Coronary Angiography (ICA) and catheterization may be considered medically necessary when ALL of the following are met:</p> <ul style="list-style-type: none"> • The patient and cardiologist together have reviewed and signed the "Invasive Coronary Angiography (ICA)" decision aid • The patient has completed and signed the "CollaboRATE" survey • Documentation of any of the following: <ul style="list-style-type: none"> o The patient is 18 years of age or younger o Congenital heart disease (CHD) o Heart failure (HF) (also known as Congestive Heart Failure or CHF) o Hypertrophic cardiomyopathy (HCM) o Kawasaki disease (KD) (also known as mucocutaneous lymph node syndrome) o Post-cardiac transplant in a patient who has not undergone coronary angiography in the previous six months o Pulmonary artery extrinsic compressions of left main coronary artery o Valvular heart disease o Return of angina within 9 months of percutaneous coronary intervention (PCI) | <p>Elective Invasive Coronary Angiography (ICA) BSC2.13</p> <p>Policy Statement: This medical policy is NOT intended to address ICA for acute coronary syndrome (ACS) or other high-risk situations as addressed in the Policy Guidelines:</p> <ol style="list-style-type: none"> I. <i>Unstable</i> angina or Non-ST-elevation myocardial infarction (NSTEMI) II. High Risk for Coronary Artery Disease III. Post-Acute Myocardial Infarction IV. Other High-Risk Factors <p>Policy Statement: Elective (NOT emergent) Invasive Coronary Angiography (ICA) and catheterization may be considered medically necessary when ALL of the following are met:</p> <ol style="list-style-type: none"> I. The patient and cardiologist together have reviewed and signed the "Invasive Coronary Angiography (ICA)" decision aid II. The patient has completed and signed the "CollaboRATE" survey III. Documentation of any of the following: <ol style="list-style-type: none"> A. The patient is 18 years of age or younger B. Congenital heart disease (CHD) C. Heart failure (HF) (also known as Congestive Heart Failure or CHF) D. Hypertrophic cardiomyopathy (HCM) E. Kawasaki disease (KD) (also known as mucocutaneous lymph node syndrome) F. Post-cardiac transplant in a patient who has not undergone coronary angiography in the previous six months G. Pulmonary artery extrinsic compressions of left main coronary artery H. Valvular heart disease I. Return of angina within 9 months of percutaneous coronary intervention (PCI) |

| POLICY STATEMENT (No changes) | |
|---|---|
| BEFORE | AFTER |
| <ul style="list-style-type: none"> o Canadian Cardiovascular Society (CCS) class I or II classification of angina (see Policy Guidelines section) with intolerance of or failure to respond to optimal medical treatment o CCS class III or IV classification of angina (with or without a response to optimal medical treatment) <p>Elective Invasive coronary angiography (ICA) and catheterization for known or suspected coronary artery disease (CAD) is considered not medically necessary for all other indications not meeting the medically necessary criteria.</p> | <ul style="list-style-type: none"> J. Canadian Cardiovascular Society (CCS) class I or II classification of angina (see Policy Guidelines section) with intolerance of or failure to respond to optimal medical treatment K. CCS class III or IV classification of angina (with or without a response to optimal medical treatment) <p>Elective Invasive coronary angiography (ICA) and catheterization for known or suspected coronary artery disease (CAD) is considered not medically necessary for all other indications not meeting the medically necessary criteria.</p> |

