



Louisiana

Coronary Computed Tomography Angiography With Selective Noninvasive Fractional Flow Reserve

Policy # 00537

Original Effective Date: 02/15/2017

Current Effective Date: 04/09/2023

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Contrast-Enhanced Coronary Computed Tomography Angiography (CCTA) for Coronary Artery Evaluation is addressed in medical policy 00153.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the use of noninvasive fractional flow reserve (FFR) following a positive coronary computed tomography angiography (CCTA) to guide decisions about the use of invasive coronary angiography (ICA) to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility may be considered for the use of noninvasive fractional flow reserve (FFR) following a positive coronary computed tomography angiography (CCTA) to guide decisions about the use of invasive coronary angiography (ICA) when **ALL** of the following criteria are met:

- The patient has symptoms consistent with myocardial ischemia; **AND**
- Symptoms persist despite maximal guideline-directed medical therapy (see Policy Guidelines); **AND**
- CCTA has been performed in the preceding 90 days; **AND**
- There is at least one 40%-90% coronary stenosis located in the proximal or middle segment of a major native coronary artery or a named branch thereof.

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

The use of noninvasive fractional flow reserve (FFR) not meeting the criteria outlined above is considered to be **investigational**.*

Policy Guidelines

Fractional flow reserve using coronary computed tomography angiography requires at least 64-slice coronary computed tomography angiography and cannot be calculated when images lack sufficient quality (11% to 13% in recent studies; e.g., in obese individuals [body mass index, >35 kg/m²]). The presence of dense arterial calcification or an intracoronary stent can produce significant beam-hardening artifacts and may preclude satisfactory imaging. The presence of an uncontrolled rapid heart rate or arrhythmia hinders the ability to obtain diagnostically satisfactory images. Evaluation of the distal coronary arteries is generally more difficult than visualization of the proximal and mid-segment coronary arteries due to greater cardiac motion and the smaller caliber of coronary vessels in distal locations.

Guideline-directed medical therapy (GDMT) consists of risk factor management and, in symptomatic patients, antianginal medications which improve quality of life.

Risk factor management:

All patients with stable CAD should be encouraged to adopt healthy lifestyles including tobacco cessation/avoidance, regular physical activity, maintenance of a healthy weight and adherence to a healthy diet. In addition, absent a contraindication, all stable CAD patients should be taking the following evidence-supported medications:

- Antiplatelet agents – Aspirin and/or P2Y₁₂ receptor antagonist
- Statin – Maximum tolerated dose of high-intensity statin (atorvastatin 40-80 mg or rosuvastatin 20-40 mg). Patients intolerant of statins and/or not reaching LDL cholesterol goal on maximum tolerated statin dose should be treated with ezetimibe, a PCSK9 inhibitor, or bempedoic acid.
- Beta blockers – In patients with a history of myocardial infarction, who have left ventricular

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systolic dysfunction (ejection fraction \leq 40%), or as an option for management of hypertension.

- ACE Inhibitor or Angiotensin Receptor Blocker – In patients with left ventricular systolic dysfunction (ejection fraction \leq 40%), diabetes, chronic kidney disease, or as an option for management of hypertension
- Antidiabetic agents – For patients who are diabetic (Hemoglobin A1c goal should be $<$ 8% in all patients although more aggressive management may be appropriate for some)

Symptom control:

Most patients with stable CAD who have symptoms should be offered anti anginal medications as an initial approach with revascularization reserved for those who have persistent unacceptable symptoms despite maximally tolerated doses.

- Beta blockers – Unless contraindicated beta blockers are first-line therapy with dose escalation until symptoms resolve or side effects develop.
- Calcium channel blockers and/or long acting-nitrates should be used as alternative initial therapy in symptomatic patients who have contraindication to, or intolerance of, beta blockers. They should also be prescribed when symptoms persist despite maximum tolerated doses of beta blockers.
- Ranolazine may be prescribed either as initial therapy in symptomatic patients who have contraindication to, or intolerance of, other antianginal medication, or for those with persistent symptoms despite treatment with other medications as described above.

Background/Overview

Stable Ischemic Heart Disease

Coronary artery disease (CAD) is a significant cause of morbidity and mortality. Various epidemiologic risk factors have been well studied. Evaluation of obstructive CAD involves quantifying arterial stenoses to determine whether significant narrowing is present. Lesions with stenosis more than 50% to 70% in diameter accompanied by symptoms are generally considered significant. It has been suggested that coronary computed tomography angiography (CCTA) or other noninvasive functional cardiac testing may help rule out CAD and avoid invasive coronary angiography (ICA) in patients with a low clinical likelihood of significant CAD. However, ICA is frequently unnecessary in patients with suspected stable ischemic heart disease, as evidenced by low

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diagnostic yields for significant obstructive CAD. Patel et al (2010) found that from a sample of over 132,000 ICAs, 48.8% of elective ICAs performed in patients with stable angina did not detect obstructive CAD (left main stenosis $\geq 50\%$ or $\geq 70\%$ in a major epicardial or branch >2.0 mm in diameter). Invasive coronary angiography is clinically useful when patients with stable angina have failed optimal medical therapy and may benefit from revascularization. A noninvasive imaging test performed before ICA as a gatekeeper, which can distinguish candidates who may benefit from early revascularization (eg, patients with unprotected left main stenosis $\geq 50\%$ or hemodynamically significant disease) from those unlikely to benefit, could avoid unnecessary invasive procedures and their potential adverse consequences. Moreover, for the large majority of patients with stable ischemic heart disease, revascularization offers no survival advantage over medical therapy; few might benefit from ICA if they have not first failed optimal medical therapy.

Clinical Risk Prediction for Stable Ischemic Heart Disease

The 2012 collaborative medical association guidelines for the diagnosis and management of patients with stable heart disease list several class I recommendations on the use of noninvasive testing in patients with suspected stable ischemic heart disease. A class I recommendation indicates that a test should be performed. In general, patients with at least intermediate risk (10% to 90% risk by standard risk prediction instruments) are recommended to have some type of test, the choice depending on the interpretability of the electrocardiogram, the capacity to exercise, and presence of comorbidity.

Clinical prediction scores or models have been developed to help estimate the pretest probability of CAD in individuals with stable chest pain. Diamond and Forrester (1979) developed the original version of a commonly cited clinical prediction model based on age, sex, and type of pain symptoms. Genders et al (2011) further studied and extended the model. Wasfy et al (2012) compared it to the Duke Clinical Score. Versteylet et al (2011) published a comparison of clinical prediction results for the Diamond and Forrester (1979) model, the Framingham risk score, the PROCAM risk score, and the SCORE risk estimation model. Min et al (2015) published another model, and in 2016 a CAD consortium developed an online calculator.

Gatekeepers to Invasive Coronary Angiography

Imposing an effective noninvasive gatekeeper strategy with one or more tests before planned ICA to avoid unnecessary procedures is compelling. The most important characteristic of a gatekeeper test is its ability to accurately identify and exclude clinically insignificant disease where

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revascularization would offer no potential benefit. From a diagnostic perspective, an optimal strategy would result in few false-negative tests while avoiding an excessive false-positive rate—it would provide a low post-test probability of significant disease. Such a test would then have a small and precise negative likelihood ratio and high negative predictive value. An effective gatekeeper would decrease the rate of ICA while increasing the diagnostic yield (defined by the presence of obstructive CAD on ICA). At the same time, there should be no increase in major adverse cardiac events (MACE). A clinically useful strategy would satisfy these diagnostic performance characteristics and impact the outcomes of interest. Various tests have been proposed as potentially appropriate for a gatekeeper function before planned ICA, including CCTA, magnetic resonance imaging, single-photon emission computed tomography, positron emission tomography, and stress echocardiography. More recently, adding noninvasive measurement of fractional flow reserve using CCTA has been suggested, combining functional and anatomic information.

Fractional Flow Reserve

Invasively measured fractional flow reserve evaluates the severity of ischemia caused by coronary artery obstructions and can predict when revascularization may be beneficial. Fractional flow reserve has not been used as a diagnostic test for ischemic heart disease, but as a test to evaluate the degree of ischemia caused by stenosis.

Invasive fractional flow reserve is rarely used in the U.S. to guide percutaneous coronary intervention (PCI). Pothineni et al (2016), using the National Inpatient Sample, reported that 201,705 PCIs were performed in 2012, but just 21,365 fractional flow reserve procedures. Assuming the intention of fractional flow reserve is to guide PCI, it would represent just 4.3% of PCI procedures. Whether noninvasively obtained fractional flow reserve will influence decisions concerning ICA, over and above anatomic considerations, is therefore important to establish empirically.

Randomized controlled trials and observational studies have demonstrated that fractional flow reserve-guided revascularization can improve cardiovascular outcomes, reduce revascularizations, and decrease costs. For example, the Fractional Flow Reserve versus Angiography for Multivessel Evaluation trial randomized 1005 patients with multivessel disease and planned PCI. At 1 year, compared with PCI guided by angiography alone, fractional flow reserve-guided PCI reduced the number of stents placed by approximately 30%, followed by lower rates (13.2% vs. 18.3%) of

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MACE (myocardial infarction, death, repeat revascularization) and at a lower cost. The clinical benefit persisted through 2 years, although by 5 years, event rates were similar between groups.

European guidelines (2013) for stable CAD have recommended that fractional flow reserve be used "to identify hemodynamically relevant coronary lesion(s) when evidence of ischaemia is not available" (class Ia), and "[r]evascularization of stenoses with fractional flow reserve <0.80 is recommended for patients with angina symptoms or a positive stress test." Other guidelines (2014) have recommended using "fractional flow reserve to identify haemodynamically relevant coronary lesion(s) in stable patients when evidence of ischaemia is not available" (class Ia recommendation). The U.S. guidelines (2012) have stated that a fractional flow reserve of 0.80 or less provides level Ia evidence for revascularization for "significant stenoses amenable to revascularization and unacceptable angina despite guideline directed medical therapy." Also, the importance of fractional flow reserve in decision making appears prominently in the 2017 appropriate use criteria for coronary revascularization in patients with stable ischemic heart disease.

Measuring fractional flow reserve during ICA can be accomplished by passing a pressure-sensing guidewire across a stenosis. Coronary hyperemia (increased blood flow) is then induced and pressure distal and proximal to the stenosis is used to calculate flow across it. Fractional flow reserve is the ratio of flow in the presence of a stenosis to flow in its absence. Fractional flow reserve levels less than 0.75 to 0.80 are considered to represent significant ischemia while those 0.94 to 1.0 are considered normal. Measurement is valid in the presence of serial stenoses, is unaffected by collateral blood flow, and reproducibility is high. Potential complications include adverse events related to catheter use such as vessel wall damage (dissection); the time required to obtain fractional flow reserve during a typical ICA is less than 10 minutes.

Fractional flow reserve using CCTA requires at least 64-slice CCTA and cannot be calculated when images lack sufficient quality (11% to 13% in recent studies, eg, in obese individuals [body mass index, >35 kg/m²]). The presence of dense arterial calcification or an intracoronary stent can produce significant beam-hardening artifacts and may preclude satisfactory imaging. The presence of an uncontrolled rapid heart rate or arrhythmia hinders the ability to obtain diagnostically satisfactory images. Evaluation of the distal coronary arteries is generally more difficult than the visualization of the proximal and mid-segment coronary arteries due to greater cardiac motion and the smaller caliber of coronary vessels in distal locations.

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Noninvasive Fractional Flow Reserve Measurement

Fractional flow reserve can be modeled noninvasively using images obtained during CCTA (HeartFlow software termed FFRCT; Siemens cFFR). The process involves constructing a digital model of coronary anatomy and calculating fractional flow reserve across the entire vascular tree using computational fluid dynamics. Fractional flow reserve using CCTA can also be used for "virtual stenting" to simulate how stent placement would be predicted to improve vessel flow.

Only HeartFlow FFRCT software has been cleared by the U.S. Food and Drug Administration (FDA). Imaging analyses require uploading data to a cloud for analysis, taking as little as 5 hours to complete. Other prototype software developed by Siemens is workstation-based with onsite analyses.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In November 2014, FFRCT simulation software (HeartFlow) was cleared for marketing by the FDA through the de novo 510(k) process (class II, special controls; FDA product code: PJA). In January 2016, the FFRCT v2.0 device was cleared through a subsequent 510(k) process.

HeartFlow FFRCT post-processing software is cleared:

"for the clinical quantitative and qualitative analysis of previously acquired Computed Tomography [CT] DICOM [Digital Imaging and Communications in Medicine] data for clinically stable symptomatic patients with coronary artery disease. It provides fractional flow reserve using coronary computed tomography angiography, a mathematically derived quantity, computed from simulated pressure, velocity and blood flow information obtained from a 3D computer model generated from static coronary CT images. Fractional flow reserve using coronary computed tomography angiography analysis is intended to support the functional evaluation of coronary artery disease. The results of this analysis [FFRCT] are provided to support qualified clinicians to aid in the evaluation and assessment of coronary arteries. The results of HeartFlow fractional flow reserve using coronary computed tomography angiography are intended to be used by qualified clinicians in conjunction with the patient's clinical history, symptoms, and other diagnostic tests, as well as the clinician's professional judgment."

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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Description

Invasive coronary angiography (ICA) is clinically useful in stable ischemic heart disease when there is coronary artery obstruction that may benefit from revascularization. However, many individuals currently undergoing ICA will not benefit from revascularization. Therefore, if there are noninvasive alternatives to guide decisions about the use of ICA to spare individuals from unnecessary ICA, there is potential to improve health outcomes. Using noninvasive measurement of fractional flow reserve as part of a noninvasive imaging strategy may be beneficial to avoid the need for ICA.

Summary of Evidence

For individuals with stable chest pain at intermediate risk of coronary artery disease (ie, suspected or presumed stable ischemic heart disease) being considered for ICA who receive noninvasive fractional flow reserve measurement following positive coronary computed tomography angiography (CCTA), the evidence includes both direct and indirect evidence: 3 meta-analyses on diagnostic performance; 1 prospective, multi-center, nonrandomized comparative study; 1 prospective, multi-center, randomized comparative study; 2 prospective cohort studies; 5 retrospective cohort studies; and 1 study reporting changes in management associated with CCTA-based strategies with selective addition of fractional flow reserve using CCTA. Relevant outcomes are test accuracy and validity, morbid events, quality of life, resource utilization, and treatment-related morbidity. The meta-analyses indicated that CCTA has high sensitivity but moderately low specificity for hemodynamically significant obstructive disease. There is direct evidence that compares health outcomes observed during 90-day to 2-year follow-up for strategies using CCTA (particularly in combination with selective fractional flow reserve measurement) with strategies using ICA or other noninvasive imaging tests. The available evidence provides support that use of CCTA with selective fractional flow reserve measurement using CCTA is likely to reduce the use of ICA in individuals with stable chest pain who are unlikely to benefit from revascularization by

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demonstrating the absence of functionally significant obstructive coronary artery disease. Also, the benefits are likely to outweigh potential harms because rates of revascularization for functionally significant obstructive coronary artery disease appear to be similar and treatment-related adverse events do not appear to increase following CCTA with a selective fractional flow reserve measurement using CCTA strategy. Moreover, given the available evidence that CCTA alone has been used to select patients to avoid ICA, the studies showing higher specificity of fractional flow reserve measurement using CCTA and lower negative likelihood ratio of fractional flow reserve measurement using CCTA compared with CCTA alone may be used to build a chain of evidence that CCTA with a selective fractional flow reserve measurement using CCTA strategy would likely lead to changes in management that would be expected to improve health outcomes by further limiting unnecessary ICA testing. While individual studies are noted to have specific methodologic limitations and some variation has been noted in the magnitude of benefit across studies, in aggregate the evidence provides reasonable support that the selective addition of fractional flow reserve measurement following CCTA results in an improvement in the net health outcome. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Heart Association, et al

In 2021, the American Heart Association, American College of Cardiology, American Society of Echocardiography, American College of Chest Physicians, Society for Academic Emergency Medicine, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance released a clinical practice guideline for the evaluation and diagnosis of chest pain. The guideline states that for "intermediate-risk patients with acute chest pain and no known coronary artery disease (CAD), with a coronary artery stenosis of 40% to 90% in a proximal or middle coronary artery on coronary computed tomography angiography (CCTA), fractional flow

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reserve with computed tomography can be useful for the diagnosis of vessel-specific ischemia and to guide decision-making regarding the use of coronary revascularization (class of recommendation [COR]: 2a (moderate; benefit >> risk); level of evidence [LOE]: B-NR (moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies or meta-analyses of such studies).\" This recommendation also applies to those intermediate-risk patients with acute chest pain and known CAD (COR: 2a; LOE: B-NR).

National Institute for Health and Care Excellence

In 2017, NICE endorsed fractional flow reserve using CCTA, with the following conclusions: \"The committee concluded that the evidence suggests that HeartFlow FFRCT is safe, has high diagnostic accuracy, and that its use may avoid the need for invasive investigations.\"

Recommendations included:

- \"The case for adopting HeartFlow FFRCT for estimating fractional flow reserve from CCTA is supported by the evidence. The technology is non-invasive and safe, and has a high level of diagnostic accuracy.\"
- \"HeartFlow FFRCT should be considered as an option for patients with stable, recent onset chest pain who are offered CCTA in line with the NICE guideline on chest pain. Using HeartFlow FFRCT may avoid the need for invasive coronary angiography and revascularization. For correct use, HeartFlow FFRCT requires access to 64-slice (or above) CCTA facilities.\"

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

In January 2018, the Centers for Medicare & Medicaid Services assigned a new technology ambulatory payment classification to HeartFlow, making Medicare-enrolled hospitals eligible for reimbursement for the technology.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 1.

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Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT02400229	Diagnostic Imaging Strategies for Patients With Stable Chest Pain and Intermediate Risk of Coronary Artery Disease: Comparative Effectiveness Research of Existing Technologies) - A Pragmatic Randomised Controlled Trial of CT Versus ICA	3546	Mar 2022
NCT02973126	Assessment of Fractional Flow reserve Computed Tomography Versus Single Photon Emission Computed Tomography in the Diagnosis of Hemodynamically Significant Coronary Artery Disease. (AFFECTS)	270	July 2022
NCT02208388	Prospective Evaluation of MyocaRdial PerFUSion ComputEd Tomography Trial	1000	Apr 2024
NCT03329469	The Value of Fractional Flow Reserve Derived From Coronary CT Angiography as Compared to CCTA or CCTA and Stress MPI in the Triage of Low to Intermediate Emergent Chest Pain Patients With Toshiba CT-FFR	1142	Mar 2024
NCT04142021	A Multicenter, Pilot Study to Evaluate Safety and Feasibility Evaluation of Planning and Execution of Surgical Revascularization Solely Based on Coronary CTA and FFRCT in Patients With Complex Coronary Artery Disease (FASTTRACK CABG)	114	Dec 2021

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NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT03702244	Prospective Randomized Trial of the Optimal Evaluation of Cardiac Symptoms and Revascularization (PRECISE)	2103	Apr 2022

NCT: national clinical trial.

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Louisiana

Coronary Computed Tomography Angiography With Selective Noninvasive Fractional Flow Reserve

Policy # 00537

Original Effective Date: 02/15/2017

Current Effective Date: 04/09/2023

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Policy History

Original Effective Date: 02/15/2017

Current Effective Date: 04/09/2023

- 10/05/2017 Medical Policy Committee review
- 10/18/2017 Medical Policy Implementation Committee approval. Policy title changed from “Noninvasive fractional Flow reserve Using Computed Tomography Angiography” to “Coronary Computed Tomography Angiography With Selective Noninvasive Fractional Flow Reserve”. Changed coverage from investigational to eligible for coverage for individuals with stable chest pain at intermediate risk of coronary artery disease being considered for invasive coronary angiography. “Positive” added before CCTA to more explicitly state that FRACTIONAL FLOW RESERVE -CT is intended for selective use following CCTA with positive results.
- 01/01/2018 Coding update
- 10/04/2018 Medical Policy Committee review
- 10/17/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 01/01/2019 Coding update
- 07/03/2019 Medical Policy Committee review
- 07/18/2019 Medical Policy Implementation Committee approval. Replaced “patients with stable chest pain at intermediate risk of coronary artery disease (CAD i.e., suspected or presumed stable ischemic heart disease [SIHD])” with “patients who meet

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coverage criteria for CCTA (as noted in medical policy 00153)” in the eligible for coverage statement.

07/02/2020 Medical Policy Committee review

07/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

07/01/2021 Medical Policy Committee review

07/14/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

07/07/2022 Medical Policy Committee review

07/13/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

01/05/2023 Medical Policy Committee review

01/11/2023 Medical Policy Implementation Committee approval. Added a Coverage Criteria section and added a guideline-directed medical therapy (GDMT) for risk factor management and symptom control to the Policy Guidelines section.

Next Scheduled Review Date: 07/2023

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0501T, 0502T, 0503T, 0504T, 0523T
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

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- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and 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 that patient's illness, injury or disease.

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