MEDICAL POLICY

POLICY TITLE	HEART TRANSPLANT
POLICY NUMBER	MP 9.007

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☐ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**1/1/2025**

I. POLICY

Human heart transplantation may be considered **medically necessary** for selected adults and children with end-stage heart failure when individual selection criteria are met.

Adult Individuals

I. Accepted Indications for Cardiac Transplantation
   1. Hemodynamic compromise due to heart failure demonstrated by any of the following three (3) bulleted items:
      - Maximal oxygen consumption (Vo_2) less than 10 mL/kg/min with achievement of anaerobic metabolism; **or**
      - Refractory cardiogenic shock; **or**
      - Documented dependence on intravenous inotropic support to maintain adequate organ perfusion; **or**
   2. Severe ischemia consistently limiting routine activity not amenable to bypass surgery or angioplasty; **or**
   3. Recurrent symptomatic ventricular arrhythmias refractory to all accepted therapeutic modalities.

II. Probable Indications for Cardiac Transplantation
   1. Maximal Vo_2 less than 14 mL/kg/min and major limitation of the individual's activities; **or**
   2. Recurrent unstable ischemia not amenable to bypass surgery or angioplasty; **or**
   3. Instability of fluid balance/renal function not due to patient noncompliance with regimen of weight monitoring, flexible use of diuretic drugs, and salt restriction.

III. The following conditions are inadequate indications for transplantation unless other factors as listed above are present.

1. Ejection fraction less than 20%; **or**
2. History of functional class III or IV symptoms of heart failure; **or**
3. Previous ventricular arrhythmias; **or**
4. Maximal Vo_2 greater than 15 mL/kg/min.

Pediatric Individuals

I. Individuals with heart failure with persistent symptoms at rest who require one or more of the following:

1. Continuous infusion of intravenous inotropic agents; **or**
2. Mechanical ventilatory support; **or**
3. Mechanical circulatory support.

II. Individuals with heart disease and symptoms of heart failure who do not meet the above criteria but who have:

1. Severe limitation of exercise and activity (if measurable, such individuals would have a maximum Vo2 less than 50% predicted for age and sex); **or**
2. Cardiomyopathies or previously repaired or palliated congenital heart disease and significant growth failure attributable to the heart disease; **or**
3. Near sudden death and/or life-threatening arrhythmias untreatable with medications or an implantable defibrillator; **or**
4. Restrictive cardiomyopathy with reactive pulmonary hypertension; **or**
5. Reactive pulmonary hypertension and risk of developing fixed, irreversible elevation of pulmonary vascular resistance that could preclude orthotopic heart transplantation in the future; **or**
6. Anatomical and physiological conditions likely to worsen the natural history of congenital heart disease in infants with a functional single ventricle; **or**
7. Anatomical and physiological conditions that may lead to consideration for heart transplantation without systemic ventricular dysfunction.

Heart retransplantation after a failed primary heart transplant may be considered **medically necessary** in individuals who meet criteria for heart transplantation.

Heart transplantation is considered **investigational** in all other situations. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

POLICY GUIDELINES

POLICY TITLE	HEART TRANSPLANT
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General Criteria

Potential contraindications for solid organ transplant are subject to the judgment of the transplant center include the following:

- Known current malignancy, including metastatic cancer; **or**
- Recent malignancy with high risk of recurrence; **or**
- Untreated systemic infection making immunosuppression unsafe, including chronic infection; **or**
- Other irreversible end-stage disease not attributed to heart or lung disease
- History of cancer with a moderate risk of recurrence; **or**
- Systemic disease that could be exacerbated by immunosuppression; **or**
- Psychosocial conditions or chemical dependency affecting ability to adhere to therapy

Policy specific potential contraindications include:

- Pulmonary hypertension that is fixed as evidenced by pulmonary vascular resistance greater than 5 Wood units, or transpulmonary gradient greater than or equal to 16 mm/Hg despite treatment*; **or**
- Severe pulmonary disease despite optimal medical therapy, not expected to improve with heart transplantation*.

*Some individuals may be candidates for combined heart-lung transplantation (refer to **MP 9.014, Heart/Lung Transplant**).

Individuals must meet the United Network for Organ Sharing (UNOS) guidelines for status 1A, 1B, or status 2 (and not currently be status 7).

Cardiac Specific Criteria

Specific criteria for prioritizing donor thoracic organs for transplant are provided by the Organ Procurement and Transplantation Network (OPTN) and implemented through a contract with UNOS. Donor thoracic organs are prioritized by UNOS on the basis of recipient medical urgency, distance from donor hospital, and pediatric status. Individuals who are most severely ill (status 1A) are given highest priority. The following factors are considered in assessing the severity of illness: reliance on continuous mechanical ventilation, infusion of intravenous inotropes, and/or dependency on mechanical circulatory support (i.e., total artificial heart, intra-aortic balloon pump, extracorporeal membrane oxygenator, ventricular assist device).

Additional criteria, which are considered in pediatric individuals, include diagnosis of an OPTN-approved congenital heart disease, presence of ductal dependent pulmonary or systemic circulation, and diagnosis of hypertrophic or restrictive cardiomyopathy while less than one (1) year old. Of note, pediatric heart transplant candidates who remain on the waiting list at the time of their 18th birthday without receiving a transplant continue to qualify for medical urgency status based on the pediatric criteria.

Specific criteria for prioritizing donor thoracic organs for retransplant include severe coronary allograft vasculopathy, mild or moderate coronary allograft vasculopathy with a left ventricular ejection fraction less than 45%, coronary allograft vasculopathy with restrictive physiology, or symptomatic graft dysfunction without evidence of active rejection.

Cross-references:

MP 9.014 Heart/Lung Transplant
MP 1.026 Total Artificial Hearts and Implantable Ventricular Assist Devices

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:
https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

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A heart transplant and a retransplant consist of replacing a diseased heart with a healthy donor heart. Transplantation is used for patients with refractory end-stage cardiac disease.

Solid Organ Transplantation

Solid organ transplantation offers a treatment option for patients with different types of end-stage organ failure that can be lifesaving or provide significant improvements to a patient's quality of life. Many advances have been made in the last several decades to reduce perioperative complications. Available data supports improvement in long-term survival as well as improved quality of life, particularly for liver, kidney, pancreas, heart, and lung transplants. Allograft rejection remains a key early and late complication risk for any organ transplantation. Transplant recipients require life-long immunosuppression to prevent rejection. Patients are prioritized for transplant by mortality risk and severity of illness criteria developed by the Organ Procurement and Transplantation Network and United Network for Organ Sharing (UNOS).

Heart Transplant

In 2022, 42,880 transplants were performed in the United States procured from 14,900 deceased donors and 6,400 living donors. Heart transplants were the third most common procedure with 4,109 transplants performed from both deceased and living donors in 2022. As of June 2023, there were 3,355 patients on the waiting list for a heart transplant.

Most heart transplant recipients now are hospitalized as status one patients at the time of transplant. This shift has occurred due to the increasing demand for the scarce resource of

donor organs resulting in an increased waiting time for recipients. Patients initially listed as status two candidates may deteriorate to a status one candidate before a donor organ becomes available. Alternatively, as medical and device therapy for advanced heart failure improves, some patients on the transplant list will recover enough function to be delisted. Lietz and Miller (2007) reported on survival for patients on the heart transplant waiting list, comparing the era between 1990 and 1994 with the era of 2000 to 2005. One-year survival for a UNOS status one candidate improved from 49.5% to 69.0%. Status two candidates fared even better, with 89.4% surviving 1 year compared with 81.8% in the earlier time period.

Johnson et al (2010) reported on waiting list trends in the U.S. between 1999 and 2008. The proportion of patients listed as status one increased, even as the waiting list and post-transplant mortality for this group have decreased. Meanwhile, status two patients have decreased as a proportion of all candidates. Completed transplants have trended toward the extremes of age, with more infants and patients older than age 65 years having transplants in recent years. Bakhtiyar et al (2020) evaluated survival among patients (N=95,323) wait-listed for heart transplantation between January 1, 1987, and December 29, 2017, using UNOS data. Results revealed 1-year survival on the wait list increased from 34.1% in 1987 to 1990 to 67.8% in 2011 to 2017 (difference in proportions, 0.34%; 95% confidence interval [CI], 0.32% to 0.36%; p<.001). One-year wait list survival also significantly increased for candidates with ventricular assist devices from 10.2% in 1996 to 2000 to 70% in 2011-2017 (difference in proportions, 0.60%; 95% CI, 0.58% to 0.62%; p<.001).

Alshawabkeh et al (2018) reported on the 1-year probability of the combined outcome of death or delisting due to clinical worsening for patients on the heart transplant waiting list, comparing the periods of April 1, 1986, to January 19, 1999 (early era) and January 20, 1999, to June 2, 2014 (current era). For adults without congenital heart disease (CHD), the probability of the combined outcome was lower in the current era compared with the early era, regardless of whether the patient was listed in status I (14.5% vs. 22.7%; p<.0001) or 2 (9.0% vs. 12.8%, p<.0001). When comparing the current and early eras in adults with CHD, a reduction in the probability of the combined outcome was demonstrated in those listed in status I (17.6% vs. 43.3%, respectively; p<.0001), whereas the outcome remained unchanged for those listed in status 2 (10.6% vs. 10.4%, respectively; p=.94).

In adults with CHD, factors associated with waitlist death or delisting due to clinical worsening within 1 year were also examined by Alshawabkeh et al (2016). A multivariate analysis identified that an estimated glomerular filtration rate less than 60 ml/min/1.73 m^2 (hazard ratio [HR], 1.4; 95% CI, 1.0 to 1.9; p=.043), albumin less than 3.2 g/dl (HR, 2.0; 95% CI, 1.3 to 2.9; p<.001), and hospitalization at the time of listing in the intensive care unit (HR, 2.3; 95% CI, 1.6 to 3.5; p<.001) or a non-intensive care hospital unit (HR, 1.9; 95% CI, 1.2 to 3.0; p=.006) were associated with waitlist death or delisting due to clinical worsening within 1 year.

Magnetta et al (2019) reported outcomes for children on the heart transplant waiting list, comparing the periods of December 16, 2011, to March 21, 2016 (era 1) and March 22, 2016, to June 30, 2018 (era 2). There was a significant decrease from era 1 to era 2 in the proportion of patients listed as status 1 (70% vs. 56%; p<.001), while the proportion of patients with CHD significantly increased across eras (49% to 54%; p=.018). The median time on the waitlist

increased from 68 days to 78 days (p=.005). There were no significant differences across eras in the cumulative incidence of death on the waitlist among all candidates (sub distribution HR, 0.96; 95% CI, 0.80 to 1.14; p=.63) and among those listed status 1A (sub distribution HR, 1.16; 95% CI, 0.95 to 1.41; p=.14). Graft survival at 90 days was also similar across eras in the overall population and in those with CHD (p>.53 for both).

As a consequence, aggressive treatment of heart failure has been emphasized in recent guidelines. Prognostic criteria have been investigated to identify patients who have truly exhausted medical therapy and thus are likely to derive the maximum benefit for heart transplantation. Maximal oxygen consumption (Vo_2max), which is measured during maximal exercise, is a measure suggested as a critical objective criterion of the functional reserve of the heart. The American College of Cardiology and American Heart Association have adopted Vo_2max as a criterion for patient selection. Studies have suggested that transplantation can be safely deferred in those patients with a Vo_2max greater than 14 mL/kg/min. The importance of Vo_2max has also been emphasized by the American Heart Association when addressing heart transplant candidacy. In past years, a left ventricular ejection fraction of less than 20% or a New York Heart Association class III or IV status might have been used to determine transplant candidacy. However, as indicated by the American College of Cardiology criteria, these measurements are no longer considered adequate to identify transplant candidates. These measurements may be used to identify patients for further cardiovascular workup but should not be the sole criteria for transplant.

Methods other than Vo_2max have been proposed as predictive models in adults. The Heart Failure Survival Scale and the Seattle Heart Failure Model (SHFM) are examples. In particular, the SHFM provides an estimate of 1-, 2-, and 3-year survival with the use of routinely obtained clinical and laboratory data. Information on pharmacologic and device usage is incorporated into the model, permitting some estimation on the effects of current, more aggressive heart failure treatment strategies. Levy et al (2006) introduced the model using a multivariate analysis of data from the Prospective Randomized Amlodipine Survival Evaluation-1 heart failure trial (N=1125). Applied to the data of 5 other heart failure trials, SHFM correlated well with actual survival (r=0.98). SHFM has been validated in both ambulatory and hospitalized heart failure populations, but with a noted underestimation of mortality risk, particularly in Black adults and device recipients. None of these models has been universally adopted by transplant centers.

Regulatory Status

Solid organ transplants are a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration (FDA).

The FDA regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation title 21, parts 1270 and 1271. Solid organs used for transplantation are subject to these regulations.

IV. RATIONALE

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Summary of Evidence

For individuals who have end-stage heart failure who receive a heart transplant, the evidence includes retrospective studies and registry data. Relevant outcomes are overall survival (OS), symptoms, and morbid events. Heart transplant remains a viable treatment for those with severe heart dysfunction despite appropriate medical management with medication, surgery, or medical devices. Given the exceedingly poor survival rates without transplantation for these patients, evidence of post-transplant survival is sufficient to demonstrate that heart transplantation provides a survival benefit. Heart transplantation is contraindicated for patients for whom the procedure is expected to be futile due to comorbid disease or for whom post transplantation care is expected to worsen comorbid conditions significantly. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have had a prior heart transplant complicated by graft failure or severe dysfunction of the heart who receive a heart retransplant, the evidence includes systematic reviews, retrospective studies, and registry data. Relevant outcomes are OS, symptoms, and morbid events. Despite improvements in the prognosis for many patients with graft failure, cardiac allograft vasculopathy, and severe dysfunction of the transplanted heart, heart retransplant remains a viable treatment for those whose severe symptoms persist despite treatment with other medical or surgical remedies. Given the exceedingly poor survival rates without retransplantation for patients who have exhausted other treatments, evidence of post-transplant survival is sufficient to demonstrate that heart retransplantation provides a survival benefit in appropriately selected patients. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

V. DEFINITIONS

TOP

ARRHYTHMIA refers to irregularity or loss of rhythm, especially of the heart.

CARDIOMYOPATHY is any disease that affects the heart muscle, diminishing cardiac performance.

EJECTION FRACTION refers to in cardiac physiology, the percentage of the blood emptied from the ventricle during systole.

NEW YORK HEART ASSOCIATION CLASS III refers to patients with cardiac disease, which results in marked limitation of physical activity. These patients are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.

NEW YORK HEART ASSOCIATION CLASS IV refers to patients with cardiac disease, which results in the inability to carry out any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

UNITED NETWORK FOR ORGAN SHARING (UNOS) is an organization established in 1984 to facilitate donation of organs for possible transplantation.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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

VIII. CODING INFORMATION

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

Covered when medically necessary:

Procedure Codes							
33940	33944	33945	S2152				

ICD-10-CM Diagnosis Codes	Description
I25.110	Atherosclerotic heart disease of native coronary artery with unstable angina pectoris
I25.111	Atherosclerotic heart disease of native coronary artery with angina pectoris with documented spasm

ICD-10-CM Diagnosis Codes	Description
I25.118	Atherosclerotic heart disease of native coronary artery with other forms of angina pectoris
I25.119	Atherosclerotic heart disease of native coronary artery with unspecified angina pectoris
I25.5	Ischemic cardiomyopathy
I25.6	Silent myocardial ischemia
I25.700	Atherosclerosis of coronary artery bypass graft(s), unspecified, with unstable angina pectoris
I25.701	Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris with documented spasm
I25.708	Atherosclerosis of coronary artery bypass graft(s), unspecified, with other forms of angina pectoris
I25.709	Atherosclerosis of coronary artery bypass graft(s), unspecified, with unspecified angina pectoris
I25.710	Atherosclerosis of autologous vein coronary artery bypass graft(s) with unstable angina pectoris
I25.711	Atherosclerosis of autologous vein coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.718	Atherosclerosis of autologous vein coronary artery bypass graft(s) with other forms of angina pectoris
I25.719	Atherosclerosis of autologous vein coronary artery bypass graft(s) with unspecified angina pectoris
I25.720	Atherosclerosis of autologous artery coronary artery bypass graft(s) with unstable angina pectoris
I25.721	Atherosclerosis of autologous artery coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.728	Atherosclerosis of autologous artery coronary artery bypass graft(s) with other forms of angina pectoris
I25.729	Atherosclerosis of autologous artery coronary artery bypass graft(s) with unspecified angina pectoris
I25.730	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with unstable angina pectoris
I25.731	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.738	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with other forms of angina pectoris
I25.739	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with unspecified angina pectoris
I25.750	Atherosclerosis of native coronary artery of transplanted heart with unstable angina

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ICD-10-CM Diagnosis Codes	Description
I25.751	Atherosclerosis of native coronary artery of transplanted heart with angina pectoris with documented spasm
I25.758	Atherosclerosis of native coronary artery of transplanted heart with other forms of angina pectoris
I25.759	Atherosclerosis of native coronary artery of transplanted heart with unspecified angina pectoris
I25.760	Atherosclerosis of bypass graft of coronary artery of transplanted heart with unstable angina
I25.761	Atherosclerosis of bypass graft of coronary artery of transplanted heart with angina pectoris with documented spasm
I25.768	Atherosclerosis of bypass graft of coronary artery of transplanted heart with other forms of angina pectoris
I25.769	Atherosclerosis of bypass graft of coronary artery of transplanted heart with unspecified angina pectoris
I25.790	Atherosclerosis of other coronary artery bypass graft(s) with unstable angina pectoris
I25.791	Atherosclerosis of other coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.798	Atherosclerosis of other coronary artery bypass graft(s) with other forms of angina pectoris
I25.799	Atherosclerosis of other coronary artery bypass graft(s) with unspecified angina pectoris
I25.810	Atherosclerosis of coronary artery bypass graft(s) without angina pectoris
I25.811	Atherosclerosis of native coronary artery of transplanted heart without angina pectoris
I25.812	Atherosclerosis of bypass graft of coronary artery of transplanted heart without angina pectoris
I25.82	Chronic total occlusion of coronary artery
I25.83	Coronary atherosclerosis due to lipid rich plaque
I25.84	Coronary atherosclerosis due to calcified coronary lesion
I25.85	Chronic coronary microvascular dysfunction
I25.89	Other forms of chronic ischemic heart disease
I25.9	Chronic ischemic heart disease, unspecified
I47.0	Re-entry ventricular arrhythmia
I47.1	Supraventricular tachycardia
I47.10	Supraventricular tachycardia, unspecified
I47.11	Inappropriate sinus tachycardia, so stated.
I47.19	Other supraventricular tachycardia
I47.20	Ventricular tachycardia, unspecified
I47.21	Torsades de pointes

ICD-10-CM Diagnosis Codes	Description
I47.29	Other ventricular tachycardia
I47.9	Paroxysmal tachycardia, unspecified
I49.01	Ventricular fibrillation
I49.02	Ventricular flutter
I50.1	Left ventricular failure
I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.811	Acute right heart failure
I50.812	Chronic right heart failure
I50.813	Acute on chronic right heart failure
I50.814	Right heart failure due to left heart failure
I50.82	Biventricular heart failure
I50.83	High output heart failure
I50.84	End stage heart failure
I50.89	Other heart failure
I50.9	Heart failure, unspecified
R09.02	Hypoxemia
R57.0	Cardiogenic shock
T86.22	Heart Transplant Failure

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X. POLICY HISTORY

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MP 9.007	**05/27/2020 Consensus Review**. No change to policy statements. Background, rationale summary, and references reviewed.
	11/29/2021 Consensus Review. Policy statement unchanged. Background, Rationale, and References updated.
	08/15/2022 Administrative Update. New ICD10 codes I47.20 and I47.29 added to policy; I47.2 removed. Effective 10/1/2022.
	11/01/2022 Consensus Review. No change to policy statement. FEP language revised. Background and Rationale updated.
	08/30/2023 Administrative Update. 4 ICD-10-CM codes added as part of new code update. Effective date 10/1/2023.
	09/06/2023 Consensus Review. No change to policy statement. Background updated. References reviewed and updated. No change to coding.
	01/19/2024 Administrative Update. Clinical benefit added.
	08/12/2024 Consensus Review. No change to policy statements. References reviewed and updated. Added ICD-0 code I47.21. No change to procedure codes.

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