

# **Evolut Clinical Guideline 7321 for Pericardial Disease Interventions**

<b><u>Guideline Number:</u></b> <b><u>Evolut CG 7321</u></b>	<b><u>Applicable Codes</u></b>	
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## **STATEMENT**

### **General Information**

- **It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.**
- **Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.**
- **The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.**

### **Purpose**

**Indications for determining medical necessity for Pericardial Disease Interventions.**

### **Clinical Reasoning**

**All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.**

**This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. (1-5)**

## **INDICATIONS**

### **Pericardiocentesis**

- **Pericardial effusion with one or more of the following:**
  - **cardiac tamponade**

- symptomatic moderate to large effusion non-responsive to medical therapy <sup>(6)</sup>
- pericarditis, when bacterial or neoplastic etiology suspected <sup>(6,7)</sup>
- large, idiopathic chronic effusion (> 3 months) not responsive to conventional therapy <sup>(6,7)</sup>
- large, idiopathic subacute effusion (4-6 weeks) not responsive to medical therapy with signs of right-sided chamber collapse on echocardiogram <sup>(6)</sup>
- tuberculous pericarditis (diagnosis and treatment) <sup>(6)</sup>
- purulent pericarditis (diagnosis and treatment) <sup>(6)</sup>
- pericarditis in renal failure not responding to dialysis <sup>(6)</sup>
- Pericardial cyst (symptomatic) and one or more of the following <sup>(6)</sup>:
  - congenital
  - inflammatory

## Pericardial Window

- Cardiac tamponade with one or more of the following characteristics <sup>(7)</sup>:
  - recurrent
  - loculated
  - neoplastic
- Pericardial effusion with one or more of the following characteristics <sup>(6)</sup>:
  - recurrent
  - biopsy material needed
  - not amenable to pericardiocentesis (i.e., loculated and/or posterior location)

## Intrapericardial Treatment

- Intrapericardial instillation of medications for one or more of the following:
  - tuberculous pericarditis, to reduce risk of constriction <sup>(6)</sup>
  - treatment of neoplastic effusions (i.e., cytostatic or sclerosing agents) <sup>(6,7)</sup>
  - treatment of uremic pericardial effusion (in addition to dialysis) <sup>(6)</sup>
  - purulent pericarditis, to reduce the risk of recurrence, tamponade and constriction <sup>(6,7)</sup>
  - treatment of autoreactive/lymphocytic effusion <sup>(6)</sup>

## Pericardiectomy

- Recurrent pericarditis or pericardial effusion not responsive to medical therapy <sup>(6,7)</sup>

- Chronic constrictive pericarditis with persistent and prominent symptoms (i.e., NYHA class III or IV) <sup>(6,7)</sup>
- Constrictive tuberculous pericarditis that has not improved or has deteriorated after 4-8 weeks of antituberculosis therapy <sup>(6)</sup>
- Purulent pericarditis with one or more of the following <sup>(6)</sup>:
  - dense adhesions
  - loculated or thick effusion
  - recurrent tamponade
  - persistent infection
  - progression to constriction
- Chylopericardium <sup>(6)</sup>

## Pericardioscopy

As an alternative to a surgical approach, to allow for one or more of the following <sup>(6)</sup>:

- pericardial biopsy and acquisition of fluid samples when the etiology of pericardial disease is in question
- pericardial drainage
- instillation of medication into the pericardiac sac

## CODING AND STANDARDS

### Codes

32601, 32604, 32658, 32659, 32661, 33016, 33017, 33018, 33019, 33020, 33025, 33030, 33031, 33050

### Applicable Lines of Business

<input checked="" type="checkbox"/>	<u>CHIP (Children’s Health Insurance Program)</u>
<input checked="" type="checkbox"/>	<u>Commercial</u>
<input checked="" type="checkbox"/>	<u>Exchange/Marketplace</u>
<input checked="" type="checkbox"/>	<u>Medicaid</u>
<input checked="" type="checkbox"/>	<u>Medicare Advantage</u>

## **BACKGROUND**

### **Definitions**

**Pericardiocentesis - It is a procedure done to remove fluid that has built up in the sac around the heart (pericardium) using a needle and small catheter to drain excess fluid either fluoroscopy or echocardiography guided.**

**Pericardioscopy - This procedure permits visualization and biopsy of the pericardial sac with its epicardial and pericardial layers.**

**Intrapericardial treatment - This procedure involves introduction of antineoplastic treatment in patients with neoplastic pericardial effusion in setting of metastatic malignancy.**

**Pericardial window - A pericardial window is a cardiac surgical procedure to create a communication, or 'window', from the pericardial space to the pleural cavity. The purpose of the window is to allow a pericardial effusion (usually malignant) to drain from the space surrounding the heart into the chest cavity in order to prevent a large pericardial effusion and cardiac tamponade. A pericardial window may be created by video-assisted thoracoscopy or balloon pericardiotomy by a percutaneous intervention.**

**Pericardiectomy - It is the surgical removal of a portion or all of the pericardium. It is also called pericardial stripping. The pericardium is a double-walled, membrane sac that surrounds the heart.**

### **AUC Score**

**A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. <sup>(4)</sup>**

- **Appropriate Care- Median Score 7-9**
- **May be Appropriate Care- Median Score 4-6**
- **Rarely Appropriate Care- Median Score 1-3**

### **Acronyms/Abbreviations**

**NYHA: New York Heart Association**

## **SUMMARY OF EVIDENCE**

**2015 ESC Guidelines for the diagnosis and management of pericardial diseases <sup>(6)</sup>**

**Study Design: This document is a set of guidelines developed by the Task Force for the Diagnosis and Management of Pericardial Diseases of the European Society of Cardiology (ESC), endorsed by the European Association for Cardio-Thoracic Surgery (EACTS). The guidelines summarize and evaluate all available evidence on pericardial**

**diseases to assist health professionals in selecting the best management strategies for individual patients.**

**Target Population: The guidelines are intended for health professionals involved in the care of patients with pericardial diseases, including cardiologists, cardiac surgeons, and other healthcare providers.**

**Key Factors:**

- **Epidemiology and Etiology: The guidelines cover the epidemiology, etiology, and classification of pericardial diseases, including infectious and non-infectious causes.**
- **Diagnosis and Management: Detailed recommendations are provided for the diagnosis and management of various pericardial syndromes, including acute pericarditis, recurrent pericarditis, pericardial effusion, cardiac tamponade, and constrictive pericarditis.**
- **Therapeutic Approaches: The guidelines discuss the use of anti-inflammatory therapies, colchicine, corticosteroids, and other immunosuppressive agents, as well as interventional techniques such as pericardiocentesis and pericardiectomy.**
- **Prognosis and Follow-up: The document includes information on the prognosis and follow-up of patients with pericardial diseases, emphasizing the importance of individualized patient care.**

**Clinical Update in Pericardial Diseases <sup>(7)</sup>**

**Study Design: This is a review article that provides a clinical update on pericardial diseases, focusing on recent updates in the literature regarding diagnostic evaluation, medical therapy, and invasive therapeutic procedures from the perspective of a perioperative physician.**

**Target Population: The review is aimed at anesthesiologists and perioperative physicians who manage patients with pericardial diseases, particularly in the context of interventional therapies or surgery.**

**Key Factors:**

- **Pericardial Structure and Function: The review describes the anatomy and function of the pericardium, emphasizing its role in protecting the heart and facilitating ventricular interdependence.**
- **Diagnostic Criteria: The article outlines the diagnostic criteria for acute pericarditis, including pleuritic chest pain, pericardial friction rub, diffuse ST-segment elevation, and new or worsening pericardial effusion.**
- **Imaging Techniques: The review highlights the importance of multimodal imaging techniques, such as echocardiography, cardiac magnetic resonance (CMR) imaging, and computed tomography (CT), in diagnosing pericardial diseases.**
- **Medical and Surgical Management: The article discusses the medical management of pericarditis, including the use of nonsteroidal anti-inflammatory**

drugs (NSAIDs), colchicine, and corticosteroids, as well as surgical interventions such as pericardiocentesis and pericardiectomy.

- Perioperative Considerations: The review emphasizes the need for anesthesiologists to understand the altered physiology of pericardial diseases and their impact on perioperative management, including the potential for hemodynamic instability and the importance of careful monitoring.

## **ANALYSIS OF EVIDENCE**

### **Shared Findings** <sup>(6,7)</sup>:

Both articles emphasize the importance of understanding pericardial diseases and provide detailed guidelines for diagnosis and management. They agree on several key points:

- Diagnostic Criteria: Both articles outline diagnostic criteria for acute pericarditis, including pleuritic chest pain, pericardial friction rub, diffuse ST-segment elevation, and new or worsening pericardial effusion.
- Imaging Techniques: Both articles highlight the importance of multimodal imaging techniques such as echocardiography, cardiac magnetic resonance (CMR), and computed tomography (CT) in diagnosing pericardial diseases.
- Medical Management: Both articles recommend the use of nonsteroidal anti-inflammatory drugs (NSAIDs) and colchicine as first-line agents for treating acute pericarditis. They also discuss the role of corticosteroids as a second-line option in cases where NSAIDs and colchicine are ineffective or contraindicated.
- Pericardial Effusion: Both articles discuss the management of pericardial effusion, emphasizing the need for pericardiocentesis in cases of cardiac tamponade or suspected bacterial or neoplastic etiology.

### **Conclusion** <sup>(6,7)</sup>

The evidence presented in both articles reiterates the importance of a comprehensive approach to diagnosing and managing pericardial diseases. The shared findings highlight the consensus on diagnostic criteria, imaging techniques, and medical management. The differing findings reflect the unique perspectives and target populations of each article, with Adler et al 2015 providing a broader overview for health professionals and Tuck and Townsley 2019 focusing on perioperative management for anesthesiologists and perioperative physicians.

Overall, both articles contribute valuable insights into the diagnosis and management of pericardial diseases, with each offering a unique perspective that complements the other.

## **POLICY HISTORY**

<u>Date</u>	<u>Summary</u>
<u>June 2025</u>	<ul style="list-style-type: none"> <li>● <u>Added a Summary of Evidence and Analysis of Evidence</u></li> </ul>
<u>May 2025</u>	<ul style="list-style-type: none"> <li>● <u>Added in general information statement regarding guideline criteria development by reputable sources, standard of care, and best practices</u></li> <li>● <u>No clinical changes</u></li> </ul>
<u>December 2024</u>	<ul style="list-style-type: none"> <li>● <u>This guideline replaces UM CARDIO 1369 Pericardial Disease Interventions</u></li> </ul>

## **LEGAL AND COMPLIANCE**

### **Guideline Approval**

#### **Committee**

**Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee**

#### **Disclaimer**

**Evolut Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolut uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolut Clinical Guidelines. Evolut clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolut reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.**

**Evolut Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolut Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.**

## **REFERENCES**

1. Bonow RO, Douglas PS, Buxton AE, et al. ACCF/AHA Methodology for the Development of Quality Measures for Cardiovascular Technology. *J Am Coll Cardiol.* 2011;58(14):1517-1538. doi:10.1016/j.jacc.2011.07.007
2. Fitch Kathryn, Bernstein SJ, Aguilar MD, et al. *The RAND/UCLA Appropriateness Method User's Manual.* RAND.; 2001. Accessed October 8, 2024. [https://www.rand.org/pubs/monograph\\_reports/MR1269.html](https://www.rand.org/pubs/monograph_reports/MR1269.html)
3. Hendel RC, Patel MR, Allen JM, et al. Appropriate Use of Cardiovascular Technology: 2013 ACCF appropriate use criteria methodology update. *J Am Coll Cardiol.* 2013;61(12):1305-1317. doi:10.1016/j.jacc.2013.01.025
4. Hendel RC, Lindsay BD, Allen JM, et al. ACC Appropriate Use Criteria Methodology: 2018 Update. *J Am Coll Cardiol.* 2018;71(8):935-948. doi:10.1016/j.jacc.2018.01.007
5. Patel MR, Spertus JA, Brindis RG, et al. ACCF Proposed Method for Evaluating the Appropriateness of Cardiovascular Imaging. *J Am Coll Cardiol.* 2005;46(8):1606-1613. doi:10.1016/j.jacc.2005.08.030
6. Adler Y, Charron P, Imazio M, et al. 2015 ESC Guidelines for the diagnosis and management of pericardial diseases. *Eur Heart J.* 2015;36(42):2921-2964. doi:10.1093/eurheartj/ehv318
7. Tuck BC, Townsley MM. Clinical Update in Pericardial Diseases. *J Cardiothorac Vasc Anesth.* 2019;33(1):184-199. doi:10.1053/j.jvca.2018.04.003

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