

Subject: Vena Cava Filters
Guideline #: CG-SURG-59
Status: Revised

Publish Date: 06/28/2023
Last Review Date: 05/11/2023

Description

This document addresses the clinical use of vena cava filters (inferior vena cava [IVC] filters and superior vena cava filters) in the management of acute venous thromboembolism (pulmonary embolism [PE] and deep venous thrombosis [DVT]).

Clinical Indications

Medically Necessary:

- I. Vena cava filter placement is considered **medically necessary** for *either* of the following indications:
 - A. Individual has a confirmed acute venous thromboembolism (pulmonary embolism [PE] or proximal deep vein thrombosis [DVT]) and a documented contraindication to anticoagulation therapy, including but not limited to **any** of the following:
 1. Active bleeding or severe bleeding diathesis (hypocoagulopathy); **or**
 2. Recent major surgery in the past 30 days; **or**
 3. Severe thrombocytopenia (that is, platelet count less than 50,000/mm³ [50 x 10⁹/L]); **or**
 4. History of intracranial bleeding; **or**
 5. History of active major bleeding when anticoagulated within therapeutic range; **or**
 - B. Individual has a confirmed acute venous thromboembolism (PE or proximal DVT) and **any** of the following:
 1. Individual has a documented failure to respond to therapeutic-level anticoagulation therapy (for example, history of development of pulmonary embolism or recurrent deep venous thrombosis while on therapeutic-level anticoagulation therapy); **or**
 2. Individual has poor cardiopulmonary reserve or chronic thromboembolic pulmonary hypertension.
- II. Retrieval (removal) of a vena cava filter is considered **medically necessary** when **any** of the following criteria are met:
 - A. The indication for the vena cava filter no longer exists; **or**
 - B. The indication for the vena cava filter is time-limited (for example, a short-term contraindication to anticoagulation therapy); **or**
 - C. The individual has a filter-related adverse event or complications (such as filter fracture, filter occlusion, or pulmonary embolism due to the device).

Not Medically Necessary:

- I. Prophylactic use of a vena cava filter is considered **not medically necessary** if the above criteria are not met and for all other conditions including, but not limited to:
 - A. Prevention of venous thromboembolism in individuals undergoing bariatric surgery; **or**
 - B. Severe trauma without documented venous thromboembolism; **or**
 - C. Cancer and recurrent venous thromboembolism, despite anticoagulation treatment.
- II. Use of a vena cava filter as an adjunct to anticoagulation therapy is considered **not medically necessary**.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. 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.

When services may be Medically Necessary when criteria are met:

CPT

| | |
|-------|---|
| 37191 | Insertion of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed |
| 37192 | Repositioning of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed |
| 37193 | Retrieval (removal) of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed |

ICD-10 Procedure

| | |
|---------|---|
| 02HV3DZ | Insertion of intraluminal device into superior vena cava, percutaneous approach |
| 02PY3DZ | Removal of intraluminal device from great vessel, percutaneous approach |
| 02WY3DZ | Revision of intraluminal device in great vessel, percutaneous approach |
| 06H03DZ | Insertion of intraluminal device into inferior vena cava, percutaneous approach |
| 06PY3DZ | Removal of intraluminal device from lower vein, percutaneous approach |
| 06WY3DZ | Revision of intraluminal device in lower vein, percutaneous approach |

ICD-10 Diagnosis

| | |
|---------------|---|
| I26.01-I26.99 | Pulmonary embolism |
| I27.24 | Chronic thromboembolic pulmonary hypertension |

| | |
|-------------------|--|
| 181 | Portal vein thrombosis |
| 182.210-182.221 | Embolism and thrombosis of superior/inferior vena cava |
| 182.290-182.291 | Embolism and thrombosis of other thoracic veins |
| 182.3 | Embolism and thrombosis of renal vein |
| 182.401-182.429 | Acute embolism and thrombosis of deep veins of lower extremity (unspecified, femoral, iliac) |
| 182.491-182.499 | Acute embolism and thrombosis of other specified deep vein of lower extremity |
| 182.4Y1-182.4Y9 | Acute embolism and thrombosis of unspecified deep veins of proximal lower extremity |
| 182.501-182.529 | Chronic embolism and thrombosis of deep veins of lower extremity (unspecified, femoral, iliac) |
| 182.591-182.599 | Chronic embolism and thrombosis of other specified deep vein of lower extremity |
| 182.5Y1-182.5Y9 | Chronic embolism and thrombosis of unspecified deep veins of proximal lower extremity |
| T82.515A-T82.515S | Breakdown (mechanical) of umbrella device |
| T82.525A-T82.525S | Displacement of umbrella device |
| T82.535A-T82.535S | Leakage of umbrella device |
| T82.595A-T82.595S | Other mechanical complication of umbrella device |
| T82.818A-T82.818S | Embolism due to vascular prosthetic devices, implants and grafts |
| T82.898A-T82.898S | Other specified complication of vascular prosthetic devices, implants and grafts |

When services are Not Medically Necessary:

For the procedure codes listed above when criteria are not met or for all other diagnoses not listed; or when the code describes a procedure or situation designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

Description of the Condition

Clinical risk factors for venous thromboembolism (VTE) include acute medical illness, atherosclerosis, cancer, decreased mobility, estrogen therapy, genetic disorders, obesity, pregnancy, major surgery, thrombophilic disorders, and trauma. Some of these risks are transient, such as major surgery and trauma, whereas others are permanent (Molvar, 2012). The incidence of nonfatal pulmonary embolism (PE) ranges from 400,000 to 630,000 cases per year. Between 50,000 and 200,000 deaths are directly related to PE (Caplin, 2011).

Description of the Technology: VC Filters

Vena cava filters are interventional medical devices most often implanted into the inferior vena cava just below the kidneys or, less commonly, in the superior vena cava. An IVC filter is a small cone-shaped device designed to capture an embolism, a blood clot that has broken loose from one of the deep veins in the legs, before it moves to the heart and lungs.

The primary two types of IVC filters are permanent and retrievable (temporary). Permanent IVC filters are not designed with mechanisms that permit them to be retrieved easily from a percutaneous approach. Retrievable filters are held in place by radial pressure, hooks or barbs and have features that allow percutaneous removal if needed after the risk of PE resolves. There are also convertible filters such as the VenaTech Convertible Vena Cava Filter System (B. Braun, Inc, Bethlehem, PA). After implantation, convertible filters can be changed to an open configuration which will discontinue filtration.

Placement of an IVC filter may be performed as an outpatient or inpatient procedure; however, most filter placements occur in the inpatient hospital setting because of ongoing medical therapy for acute thromboembolic disease or underlying illness. An IVC filter is typically implanted using fluoroscopy to guide the final position of the filter, or placed using transabdominal or intravascular ultrasound. Knowledge of the normal and variant anatomy of the vena cava is important for successful placement of an IVC filter and prevention of complications. Although IVC filter placement protects the pulmonary vascular bed, it does not lessen the thrombotic predisposition or the incidence of lower extremity VTE. IVC filters are typically removed once the bleeding risk is low and anticoagulation therapy is initiated to treat the source of thromboembolism.

Indications for IVC Filter Placement

Routine use of IVC filters is not recommended for the treatment and prophylaxis of VTE. The primary treatment for acute VTE is anticoagulation therapy. This may include unfractionated heparin, low molecular weight heparin (LMWH), fondaparinux, and direct oral anticoagulants (DOACs). DOACs are as effective as conventional therapy with LMWH and vitamin K antagonists. Thrombolytic therapy is reserved for massive PE or extensive DVT (Streiff, 2016). (Note: See Definitions section for anticoagulant therapy by drug class). VTE therapy includes rapid initial anticoagulation to reduce the risk of clot propagation, long-term anticoagulation to reduce the risk of VTE recurrence, followed by discontinuation of anticoagulation therapy when the risk of treatment exceeds the risk of recurrent VTE (Kearon, 2012; Kearon, 2016). The typical duration of anticoagulation therapy is at least 3 months.

Specialty medical society and professional medical groups have published guidelines for the placement of vena cava filters. Recommendations in these guidelines agree that vena cava filter placement is indicated in individuals with acute VTE and contraindications to anticoagulation therapy; however, these guidelines are not based on high-level evidence such as randomized controlled trials (RCTs).

Widely accepted and validated indications for IVC filter placement are: 1) absolute contraindication(s) to therapeutic anticoagulation; 2) failure of anticoagulation when there is acute proximal venous thrombosis; or 3) life-threatening hemorrhage on anticoagulation therapy (Jaff, 2011; Kearon, 2016; Kaufman, 2020; Meissner, 2011; Zekser, 2016). Generally agreed upon absolute (and relative) contraindications to anticoagulation therapy for the treatment of acute VTE are variably stated in the peer-reviewed medical literature and current practice guidelines. Some authors suggest that contraindications to anticoagulation therapy may be divided into two subtypes: event-related contraindications (such as, active or prior bleeding, high-risk bleeding surgery, history of intracranial hemorrhage, and major trauma) and patient-related contraindications (such as, personal preference, inability to adhere to/monitor therapy, frequent falls/frailty, and others).

There are varying opinions on the role of vena cava filters in reducing mortality or recurrent PE in individuals with other conditions, such as individuals with VTE despite anticoagulation, individuals with recent VTE requiring anticoagulation while awaiting surgery, or use as primary prevention in high-risk individuals.

The ninth edition of the ACCP evidence-based clinical practice guideline on antithrombotic therapy for VTE disease and prevention of thrombosis (Kearon, 2012) states that individuals who have an IVC filter inserted should receive a conventional course of anticoagulation (for example, parenteral and long-term anticoagulation) if the contraindication to anticoagulation therapy resolves. "The duration of anticoagulation, therefore, will vary according to whether the DVT was provoked by a temporary risk factor, was unprovoked, or was associated with cancer, and may be influenced by the patient's ongoing risk of bleeding and preferences." This recommendation "...is weaker than for anticoagulation of most patients with VTE because the risks of bleeding may remain elevated,

and the patient's risk of recurrence is expected to be lower if the acute episode of thrombosis occurred remotely." The ACCP considers the evidence to be "moderate" for IVC filter use in individuals with acute proximal DVT who cannot be treated with anticoagulation, "...because of serious imprecision and indirectness (ie, extrapolated from the PREPIC study in which patients were routinely treated with anticoagulants; this indirectness, however, is minor)." The ACCP recommendations for the use of an IVC filter to treat DVT of the leg are summarized as follows (Grade 1: strong; Grade 2: weak; based on high- (Grade A), moderate- (Grade B), and low- (Grade C) quality evidence):

- 2.13.1. In patients with acute DVT of the leg, we recommend against the use of an IVC filter in addition to anticoagulants (Grade 1B).
- 2.13.2. In patients with acute proximal DVT of the leg and contraindication to anticoagulation, we recommend the use of an IVC filter (Grade 1B).
- 2.13.3. In patients with acute proximal DVT of the leg and an IVC filter inserted as an alternative to anticoagulation, we suggest a conventional course of anticoagulant therapy if their risk of bleeding resolves (Grade 2B).

For the initial treatment of PE (as previously noted in the above section 2.13.1-2.13.3), the ACCP guideline (Kearon, 2012) recommends use of IVC filters instead of initial anticoagulant therapy in individuals with acute PE if there is an unacceptable risk of bleeding or as an adjunct to anticoagulation. "As in DVT, no randomized trials or prospective cohort studies have evaluated IVC filters as sole therapy for acute PE" (that is, without concurrent anticoagulation, as studied in the PREPIC trial). If an individual has an acute PE and a short-term contraindication to anticoagulation, provided there is no proximal DVT on ultrasound, the guideline recommends that it is reasonable to not insert an IVC filter immediately; "serial ultrasound examinations can be performed to ensure that the patient remains free of proximal DVT while anticoagulation is withheld." In addition, the guideline states there is "uncertainty about the risk and benefits of inserting IVC filters as an adjunct to anticoagulant and thrombolytic therapy in patients with PE and hypotension." The guideline cites outcomes reported from individuals with hemodynamic compromise in the International Cooperative Pulmonary Embolism Registry, where insertion of an IVC filter was associated with a reduction of early recurrent PE and death (Kucher, 2006); thus, the ACCP recommendation against insertion of an IVC filter in individuals with acute PE who are treated with anticoagulants "may not apply to this select subgroup of patients." The ACCP recommendations for use of IVC filters for the initial treatment of PE are summarized as follows:

- 5.9.1. In patients with acute PE who are treated with anticoagulants, we recommend against the use of an IVC filter (Grade 1B).
- 5.9.2. In patients with acute PE and contraindication to anticoagulation, we recommend the use of an IVC filter (Grade 1B).
- 5.9.3. In patients with acute PE and an IVC filter inserted as an alternative to anticoagulation, we suggest a conventional course of anticoagulant therapy if their risk of bleeding resolves (Grade 2B).

In 2016, the ACCP published updated guidelines on antithrombotic therapy for VTE disease and confirmed the recommendations in their 2012 document (Kearon, 2012), stating "In patients with acute DVT or PE who are treated with anticoagulants, we recommend against the use of an inferior vena cava (IVC) filter (Grade 1B)" (Kearon, 2016). Since publication of the PREPIC trial results (Decousus, 1998; PREPIC, 2005), the ACCP guideline states that "several registries have suggested that IVC filters can reduce mortality in patients with acute VTE, although this evidence has been questioned" (eg, Muriel, 2014; Prasad, 2013; Stein, 2012; Stein, 2014). In 2015, Mismetti and colleagues published outcomes of the PREPIC 2 open-label, RCT which found that placement of an IVC filter for 3 months did not reduce recurrent PE, including fatal PE, in anticoagulated individuals with PE and DVT who had additional risk factors for recurrent VTE. The outcomes of this trial are consistent with the current ACCP recommendations.

The Society of Interventional Radiology (SIR) guidelines (revised by the American College of Radiology (ACR) in collaboration with SIR) (Caplin, 2011) for the performance of IVC filter placement for the prevention of PE includes indications for therapeutic placement of an IVC filter in the presence of documented PE or IVC, iliac, or femoropopliteal DVT, and one of more of the following:

- Absolute or relative contraindication to anticoagulation;
- Complication of anticoagulation;
- Failure of anticoagulation;
- Recurrent PE despite adequate therapy;
- Inability to achieve/maintain adequate anticoagulation;
- Propagation/progression of DVT during therapeutic anticoagulation;
- Massive PE with residual DVT in a patient at risk for further PE;
- Free-floating iliofemoral or IVC thrombus; and
- Severe cardiopulmonary disease and DVT (eg, cor pulmonale with pulmonary hypertension).

In 2020, SIR published guidelines on IVC filter use in the treatment of VTE (Kaufman, 2020). The following selected recommendations are indications for which the 2020 SIR guidelines recommend that IVC filters be considered:

"In patients with acute PE with a contraindication to anticoagulation therapy, we suggest an IVC filter be considered based on various clinical risk factors, as outlined in the rationale."

"In patients with acute DVT without PE and with a contraindication to anticoagulation therapy, we suggest that an IVC filter be considered based on various clinical risk factors, as outlined in the rationale."

"In patients undergoing anticoagulation for acute VTE (DVT, PE) in whom a contraindication to anticoagulation develops, we suggest that an IVC filter be considered in the setting of ongoing significant clinical risk for PE."

The following are selected indications for which the 2020 SIR guidelines recommend against routine placement of IVC filters, or recommend use only in select individuals:

"In patients undergoing extended anticoagulation for VTE (DVT, PE) and have completed the acute phase of treatment in whom a contraindication to anticoagulation develops, we suggest that an IVC filter not be placed, with rare exceptions."

"In patients who are receiving therapeutic anticoagulation for VTE (DVT, PE) who experience a recurrent VTE, we suggest that a filter not be placed, with few exceptions. Reasons for anticoagulation failure should always be addressed."

"In patients with acute VTE (DVT, PE) who are being treated with therapeutic anticoagulation, we recommend against routine placement of an IVC filter."

"In trauma patients without known acute VTE, we recommend against the routine placement of IVC filters for primary VTE prophylaxis."

"In patients without known acute VTE who are undergoing major surgery, we suggest against routine placement of IVC filters."

The SIR guidelines do not delineate absolute or relative contraindications to anticoagulation therapy for the treatment of acute VTE.

The American Heart Association statement (AHA) (Jaff, 2011) has published a scientific statement that includes the following recommendations for placement of an IVC filter in the setting of acute PE:

- Adult patients with any confirmed acute PE (or proximal DVT) with contraindications to anticoagulation or with active bleeding complication should receive an IVC filter (Class I; Level of Evidence B).
- For patients with recurrent acute PE despite therapeutic anticoagulation, it is reasonable to place an IVC filter (Class IIa; Level of Evidence C).
- Placement of an IVC filter may be considered for patients with acute PE and very poor cardiopulmonary reserve, including those with massive PE (Class IIb; Level of Evidence C).
- An IVC filter should not be used routinely as an adjuvant to anticoagulation and systemic fibrinolysis in the treatment of acute PE (Class III; Level of Evidence C).

Nicolaides and colleagues (2016), on behalf of the Cardiovascular Disease Educational and Research Trust, European Venous Forum, North American Thrombosis Forum, and International Union of Angiology and Union Internationale du Phlebologie, categorized indications for IVC filter insertion as absolute, relative, and prophylactic, with the term "prophylactic" used to describe "the indication for patients at risk who have no identifiable pulmonary embolism (PE) or deep venous thrombosis." Absolute indications for IVC filter insertion in individuals with VTE include: (1) venous thromboembolic complications associated with a contraindication to anticoagulation, (2) documented failure of anticoagulation, or (3) complications of anticoagulation. Relative indications exist for individuals with existing VTE and high risk of PE despite anticoagulation; or when the risk of bleeding complications would be high with anticoagulation, including large free-floating thrombus in the vena cava, massive PE, or DVT in individuals with limited cardiopulmonary reserve or who are suspected to be noncompliant with anticoagulation. Prophylactic indications exist in individuals who have neither DVT nor PE but in whom the perceived risk of VTE is high and the efficacy of alternative forms of prophylaxis is considered poor or associated with high bleeding risk. The level of evidence to support of these indications for IVC filter placement are as follows:

- Patients who have PE or proximal DVT with contraindications to anticoagulation should receive an IVC filter (level of evidence: moderate).
- Patients who have recurrent acute PE despite therapeutic anticoagulation should receive an IVC filter (level of evidence: low).
- Patients with acute PE and poor cardiopulmonary reserve should be considered for an IVC filter (level of evidence: low).
- Patients who receive a retrievable IVC filter should be evaluated for filter removal within the specific filter's retrieval window (level of evidence: low).
- An IVC filter should not be used routinely as an adjunct to anticoagulation (level of evidence: low).
- Patients receiving an IVC filter due to a contraindication to anticoagulation should be restarted on anticoagulation whenever the contraindication no longer exists (level of evidence: low).

The 2019 ACR Appropriateness Criteria on inferior vena cava filters related to radiologic management of VTE includes the following recommendations:

- Acute VTE with no contraindication to anticoagulants:
 - Anticoagulation: Usually appropriate:
 - Retrievable IVC filter: May be appropriate:
 - Permanent IVC filter: Usually not appropriate.
- Acute VTE with contraindication to anticoagulation, major complication of anticoagulation or failure of anticoagulation:
 - Retrievable IVC filter: Usually appropriate:
 - Permanent IVC filter: May be appropriate:
 - Observation: Usually not appropriate.

In 2016, White and colleagues reported on a retrospective analysis of observational data obtained from all noncancer patients admitted to nonfederal California hospitals for acute VTE from 2005 to 2010. The study population was stratified by the presence or absence of a contraindication to anticoagulation therapy. Principal study outcomes were death within 30 and 90 days, recurrent VTE manifested as PE (with or without DVT), or DVT alone within 1 year of hospital discharge. A recurrent VTE event after the index admission was defined by a hospital readmission or an emergency department visit with a principal diagnosis of acute DVT or PE or by a diagnosis of acute VTE during a subsequent hospitalization that was within the specified follow-up time period. Among 80,697 individuals without a contraindication to anticoagulation, vena cava filter use (n=7762, 9.6%) did not significantly reduce the 30-day risk of death (hazard ratio [HR] 1.12; 95% confidence interval [CI], 0.98-1.28). However, in individuals with active bleeding, vena cava filter (n=1095, 36.3%) placement reduced the 30-day risk of death by 32% (HR 0.68; 95% CI, 0.52-0.88) and the 90-day risk by 27% (HR 0.73; 95% CI, 0.59-0.90). Among 1445 individuals who underwent major surgery, vena cava filter use (n=489, 33.8%) did not reduce mortality (HR 1.1; 95% CI, 0.71-1.77). Subgroup analysis identified that vena cava filter use did not reduce the risk of subsequent PE.

Turner and colleagues (2018) focused on individuals with VTE who have contraindications to anticoagulation, the population in which vena cava filter placement is most often recommended. The study included inpatient hospital data from 3 states and identified individuals who had been hospitalized with a diagnosis of DVT or PE and a contraindication to anticoagulation. A total of 126,030 individuals were included in the analysis. 45,771 (36.3%) received an IVC filter and 80,259 (63.7%) did not receive an IVC filter. In a multivariate analysis, use of an IVC filter significantly increased the risk of mortality at 30 days (HR, 1.18; 95% CI, 1.13 to 1.22; p<0.001). While a potential increased mortality risk is concerning, the study has several methodological issues that make the findings inconclusive. As discussed in an accompanying editorial by Secernsky and colleagues, it was not clear whether individuals had VTE at hospital admission, or developed it later or whether IVC placement was done before or after individuals developed VTE. In addition, the authors of the editorial noted that about two-thirds of the individuals in the study population, all of whom were classified as having contraindications to anticoagulation, did not have VTE placement suggesting that either guidelines were not followed or these individuals were misclassified and did not actually meet criteria. The findings of the Turner study require further study for confirmation.

VC Filter Removal

According to the AHA (Jaff, 2011), removal of a retrievable IVC filter should be considered when the indication for placement no longer exist or the individual no longer has contraindications to anticoagulation. The AHA statement also recommends placement of a permanent, nonretrievable IVC filter in the following circumstances:

- individuals with iliofemoral deep vein thrombosis (DVT) and a long-term contraindication to or a complication of anticoagulation therapy (Class IIa; Level of Evidence C),
- individuals with symptomatic PE despite therapeutic-level anticoagulation, or
- individuals with severe cardiorespiratory compromise.

The AHA's recommendation for an individual with iliofemoral DVT and a time-limited indication for an IVC filter state that, "placement

of a retrievable IVC filter is reasonable" (Class IIa, Level of Evidence C [based on expert consensus, limited data on the feasibility of filter placement and retrieval, and limited data on the associated short-term clinical outcomes]). Additionally, individuals "who receive retrievable IVC filters should be evaluated periodically for filter retrieval within the specific filter's retrieval window (Class I; Level of Evidence C)."

In 2014, the U.S. Food and Drug Administration (FDA) posted an initial communication concerning removal of retrievable IVC filters after receiving reports of adverse events and product problems associated with them. Some of these events led to adverse clinical outcomes and may be related to how long the filter had been implanted. The FDA stated, "for patients with retrievable filters, some complications may be avoided if the filter can be removed once the risk of pulmonary embolism has subsided." The FDA has expressed concern that retrievable IVC filters are not always removed once a short-term risk subsides. Thus, the FDA has made the following recommendations:

- The FDA recommends that implanting physicians and clinicians responsible for the ongoing care of patients with retrievable IVC filters consider removing the filter as soon as protection from pulmonary embolism is no longer needed.
- The FDA encourages all physicians involved in the treatment and follow-up of patients receiving IVC filters to consider the risks and benefits of filter removal for each patient. A patient should be referred for IVC filter removal when the risk/benefit profile favors removal and the procedure is feasible given the patient's health status.

Concurrent Use of VC Filters and Anticoagulation Therapy in Acute DVT or PE

Studies suggest there is lack of benefit to the use of IVC filters in addition to anticoagulation in individuals with acute VTE already on anticoagulation with no absolute contraindications (Decousus, 1998; Kearon, 2012; Kearon, 2016; Mismetti, 2015; PREPIC Study Group, 2005). The current ACCP guidelines for antithrombotic therapy for VTE disease (Kearon, 2016) recommend against the routine use of IVC filters in individuals with acute DVT or PE who are being treated with anticoagulation therapy (Grade 1B; Strong recommendation, based on moderate quality evidence).

The ACCP recommendation is primarily based on the findings of the Prevention du Risque d'Embolie Pulmonaire par Interruption Cave (PREPIC) trial (Decousus, 1998). The PREPIC trial randomized 400 participants with proximal DVT or PE to either anticoagulation alone or anticoagulation plus IVC filter placement. The 8-year follow-up study (PREPIC Study Group, 2005) of participants from the initial 2-year PREPIC study reported that placement of a permanent IVC filter was associated with a reduction in the initial rate of PE. However, placement of the permanent IVC filter was also associated with an increase in the rate of DVT and it did not influence the total occurrence of VTE (DVT and PE combined). There was no difference in mortality.

A subsequently published randomized, open-label, controlled trial called PREPIC 2 (Mismetti, 2015) examined the adjuvant role of IVC filters in 399 individuals with acute PE at high risk for recurrence. High risk was defined as age over 75 years, active cancer, chronic respiratory failure, DVT involving segment, bilateral DVT, or evidence of right biventricular strain or myocardial injury. Study participants received either anticoagulation therapy alone or anticoagulation therapy plus an IVC filter. In the IVC filter group (n=193), filters were successfully retrieved at 3 months from placement in 153 of the 164 participants in whom retrieval was attempted. The investigators found no difference at 3 or 6 months in outcomes including rates of recurrent VTE, major bleeding, or mortality between the groups.

As all participants in the PREPIC trial received anticoagulation therapy, the trial outcomes provide minimal guidance in IVC filter placement in individuals who are unable to be treated with anticoagulation therapy. The ACCP guidelines (Kearon 2016) did not compare the results of the PREPIC and PREPIC 2 studies because of differences in the type of filters used, the duration of filter placement, and differences in the length of follow-up. That ACCP guideline stated that there is uncertain benefit from the use of IVC filters in anticoagulated patients with severe PE.

Spencer and colleagues (2010) reported similar results to the PREPIC trial in a population based VTE observational study. At 3 years, the rate of PE was reported for participants treated with an IVC filter (1.7%) compared with those without an IVC filter (5.3%; p=0.18). The incidence of recurrent DVT was 21% for participants treated with an IVC filter and 14.9% for those treated without an IVC filter (p=0.009). The subjects who received an IVC filter in this trial thus had a higher rate of recurrent DVT with a rate of PE that was not statistically lower than those treated without a filter.

To date, no clinical trial has reported outcomes directly comparing the effectiveness of anticoagulation therapy alone with IVC filter placement for the treatment of individuals with acute DVT or PE.

Prophylactic Placement of VC Filters

The 2019 American Society of Hematology (ASH) guideline on prevention and management of VTE in surgical hospitalized individuals includes the following provisional recommendation against prophylactic use of IVC (Anderson, 2019):

For patients undergoing major surgery, the ASH guideline panel suggests against using inferior vena cava (IVC) filters for prophylaxis of VTE (provisional recommendation based on very low certainty in the absence of evidence).

In a Cochrane review, Young and colleagues (2010) evaluated RCTs examining the efficacy of vena cava filters in preventing PE. The two studies eligible for inclusion in the review involved a total of 529 participants (Decousus, 1998; Fullen, 1973). The Cochrane review authors did not combine study findings in a meta-analysis. They concluded that no recommendations for vena cava filter use can be drawn from the available RCTs.

Severe Trauma

Individuals who experience trauma are at increased risk for VTE due to several factors including endothelial damage, hypercoagulability, and long periods of immobility (Molvar, 2012).

As noted above, the 2020 SIR guidelines (Kaufman, 2020) states:

"In trauma patients without known acute VTE, we recommend against the routine placement of IVC filters for primary VTE prophylaxis."

The 2020 SIR guideline states the following in the discussion of the recommendation on major trauma:

Benefits and harms.—Routine prophylactic filter placement has not been demonstrated to result in improvement in mortality following injury in patients who receive appropriate pharmacoprophylaxis. In fact, routine placement is associated with an increased rate of DVT, which is worsened when retrievable filters are not routinely removed. A potential benefit may exist in patients who cannot undergo adequate and appropriate pharmacoprophylaxis. Therefore, the panel judged that the balance of desirable and undesirable effects probably favors the comparison.

For evidence of potential harms, the guideline cites Fullen (1973):

Fullen et al (30) randomized patients diagnosed with traumatic fracture of the proximal femur to insertion of an IVC filter or no filter. Lower rates of PE were shown following injury in patients who had filter placement compared with those who did not (2% vs 20%). However, it is important to note that this study was performed before routine use of pharmacoprophylaxis that is known to mitigate the risk of VTE (PE, DVT).

The 2019 ACR Appropriateness Criteria stated that VTE prophylaxis in high-risk individuals, such as those with major trauma or traumatic brain injuries, retrievable IVC filter placement is usually appropriate and permanent IVC filter placement is usually not appropriate.

Haut and colleagues (2014) performed a systematic review and meta-analysis of eight studies (n=4592 subjects) published through July 2012 comparing treatment with or without prophylactic IVC filter placement in preventing PE, fatal PE, and mortality in trauma subjects. Seven of the eight studies were observational; six of the eight studies were published more than 20 years ago in a different diagnostic and therapeutic environment. No studies included comparisons of current practice, such as use of retrievable filters or newer anticoagulation therapies. The evidence showed a consistent reduction of PE (Relative Risk [RR] 0.20; 95% CI, 0.06-0.70; $I^2=0\%$) and fatal PE (RR 0.09; 95% CI, 0.01-0.81; $I^2=0\%$) with IVC filter placement, without any statistical heterogeneity. There was no significant difference found in the incidence of DVT (RR 1.75; 95% CI, 0.50-6.19; $p=0.38$; $I^2=56.8\%$) or mortality (RR 0.70; 95% CI, 0.40-1.23; $I^2=6.7\%$). The authors reported the number needed to treat to prevent one additional PE with IVC filters was estimated to range from 109 (95% CI, 93-190) to 962 (95% CI, 819-2565), depending on the baseline PE risk. Although the strength of evidence was low, the authors concluded that, among severely injured individuals who are unable to receive pharmacologic prophylaxis due to high bleeding risk, there are individuals likely to benefit from a retrievable IVC filter with a lower incidence of PE and fatal PE.

In 2019, Ho and colleagues published an RCT on early prophylactic placement of vena cava filters in 240 individuals with contraindications to anticoagulant use in the first 72 hours after admission. Participants were assigned to retrievable vena cava filter placement or no filter placement. Filters were removed when prophylactic anticoagulation could be safely initiated, or before 90 days. The primary endpoint, a composite of symptomatic PE and death from any cause at 90 days after enrollment, did not differ significantly between groups. The endpoint was attained by 13.9% of individuals in the vena cava filter group and 14.4% of the control group (HR, 0.99; 95% CI, 0.51-1.94, $p=0.98$). By 7 days after the severe injury, 67% of individuals were able to receive anticoagulants. Among those with continued contraindications, symptomatic PE from day 8 to day 90 after injury occurred in 0/46 individuals in the vena cava filter group and 5/34 (15%) in the control group. The trial was designed to detect a large difference between groups in the primary outcome and was underpowered to detect a moderately lower incidence of the primary endpoint.

Shariff and colleagues (2021) performed a meta-analysis probing the prophylactic use of IVC filters on the development of symptomatic or fatal PE with major trauma. The inclusion criteria were randomized and observational controlled trials that investigated the prophylactic use of IVC filter placement among individuals with major trauma. The researchers defined major trauma as injury severity score (ISS) of > 15 or any trauma delaying the initiation of VTE pharmacological prophylaxis therapy for DVT. A total of 10 studies with 2290 subjects with major trauma were included. There were 2 RCTs and 8 controlled observational studies in the analysis. Two of the authors conducted the data extraction using the Mantel-Haenszel method with a random-effect model to calculate RR with 95% CI. The researchers rated both of the RCTs as having a high risk of bias because the trials were not blinded. The other 8 observational studies were also noted as having a high risk of bias. The results found that the prophylactic use of IVC filters was associated with a lower risk of symptomatic PE in individuals with major trauma (RR 0.27; CI 0.12–0.58; $p<0.05$; $I^2 = 0\%$, $\chi^2 p=0.85$). In addition, the prophylactic use of IVC filters was not associated with a decreased risk of fatal PE in individuals with major trauma (RR 0.29, CI 0.08–1.10, $p=0.07$; $I^2 = 0\%$, $\chi^2 p=0.73$). Limitations identified with the meta-analysis included the small number of RCTs and limited information that was available regarding complications associated with prophylactic IVC filter insertion. The researchers noted future trials were warranted that studied IVC filters for individuals with major trauma.

VC Filter Placement in Special Populations

Bariatric Surgery

The clinical utility of vena cava filter placement in individuals undergoing bariatric surgery is unclear. Traditional methods of thromboprophylaxis used during bariatric surgery procedures includes sequential calf compression devices and perioperative LMWH.

Rowland and colleagues (2015) performed a systematic review of the literature on the use of IVC filters for the prevention of VTE in obese individuals undergoing bariatric surgery. A total of 18 studies with highly heterogeneous data were included in the review. No randomized controlled trials were found. The evaluable data from controlled cohort studies suggested that those individuals who have an IVC filter inserted preoperatively may be at higher risk of developing DVT and PE. A small cohort of individuals with multiple risk factors for VTE benefitted from reduced PE-related mortality after preoperative IVC filter insertion. A total of 12 case series reporting VTE outcomes from 497 individuals who underwent preoperative IVC filter insertion and demonstrated DVT rates of 0% to 20.8% and PE rates ranging from 0% to 6.4%. The review concluded that there was no evidence to suggest the potential benefits of IVC filters outweighed the significant risks of therapy when placed preoperatively in individuals undergoing bariatric surgery.

The 2019 ACR Appropriateness Criteria state that IVC filters are not generally recommended for individuals undergoing bariatric surgery.

Iliofemoral DVT and Catheter-Directed Thrombolysis (CDT)

The Society for Vascular Surgery and the American Venous Forum addresses the use of periprocedural IVC filters in a clinical practice guideline on early thrombus removal strategies for acute DVT (Meissner, 2012). The guideline recommends against routine use of IVC filters (permanent or temporary) in conjunction with catheter-directed pharmacologic thrombolysis of the iliofemoral venous segments (Grade of recommendation, 1: Strong; Quality of evidence: C. Low or very low). However, the guideline suggests that the relative risks and benefits of periprocedural retrievable IVC filter placement should be considered in individuals undergoing pharmacomechanical thrombolysis and those with thrombus extending into the IVC or having markedly limited cardiopulmonary reserve (Grade of recommendation, 2: Weak; Quality of evidence: C. Low or very low).

The AHA scientific statement (Jaff, 2011) recommends against periprocedural IVC filter placement for most individuals with iliofemoral DVT undergoing drug-only infusion CDT. Preprocedure placement and postprocedure removal of retrievable IVC filters “may be reasonable in carefully selected iliofemoral DVT patients undergoing pharmacomechanical CDT or stand-alone percutaneous mechanical thrombectomy (PMT), depending on the thrombus extent, patient factors such as baseline cardiopulmonary status, and the specific clot-removal methods that will be used.”

Pregnancy

The American College of Obstetricians and Gynecologists (ACOG) practice guidelines recommend insertion of a temporary IVC filter in pregnant women with acute VTE and contraindications to anticoagulant therapy (Branch, 2012; McLintock, 2012), or in those with

recurrent VTE despite therapeutic anticoagulation (James, 2011). The ACCP guidance for the treatment and prevention of obstetric-associated VTE (Bates, 2012) stated that insertion of a temporary IVC filter is best restricted to women with proven DVT who have recurrent PE despite adequate anticoagulation.

Cancer-Associated Venous Thromboembolic Disease

The 2021 guideline from ASH (Anderson, 2021) on VTE included the following recommendation:

For patients with cancer and recurrent VTEs, despite anticoagulation treatment, the ASH guideline panel suggests not using an IVC filter over using a filter (conditional recommendation, very low certainty in the evidence of effects).

Remarks: An IVC filter may be required if there is a contraindication to anticoagulation therapy (active bleeding or urgent surgery required). If an IVC filter is required, a retrievable filter is preferred, and it should be removed once anticoagulation can be safely resumed.

A large cohort study (not cited in the 2021 ASH guideline) was published by Balabhadra and colleagues (2020). The study included 88,585 individuals with malignant neoplasms who were diagnosed with acute lower extremity DVT. Data were from a database of inpatient care in two U.S. states. A total of 33,740 individuals (38.1%) underwent IVC filter placement; most (80%) of these procedures occurred within 30 days of DVT diagnosis. There were 33,057 (38.4%) individuals who received systemic anticoagulation, 39.7% of those who got IVCs and 29.0% of those who did not get IVCs. Data were not reported on the timing of anticoagulation versus IVC filter placement. A new DVT developed in 19,426 (21.9%) individuals, 28.5% of those who got IVCs and 17.9% of those who did not get IVCs ($p < 0.001$). In a multivariate matched propensity analysis controlling for potential confounding factors, the proportion of new DVTs remained lower in individuals who received IVCs (18.7%) compared with those who did not get IVCs (22.1%), $p < 0.001$. A new PE, developed in 4492 of the 85,585 individuals (5.1%); the rate of new PE in the groups that did and did not undergo IVC filter placement was not reported. In the unadjusted analysis, individuals who underwent IVC filter placement had worse overall in-hospital mortality than those who did not get IVCs. However, in the multivariate analysis, there was significant improvement in PE-free survival in individuals who got IVCs compared with those who did not get IVCs (HR, 0.69; 95% CI, 0.64 to 0.75; $p < 0.001$). A limitation of this study was that it did not randomize individuals to treatment group; however, it had a large sample size and attempted to control for confounding variables by conducting a multivariate analysis. Moreover, data were not presented on IVC filter use in individuals who did and did not receive or have contraindications to anticoagulation.

The National Comprehensive Cancer Network (NCCN®) clinical practice guideline in oncology for cancer-associated venous thromboembolic disease treatment algorithm (V1.2022) includes a category 2A recommendation for placement of an IVC filter ("retrievable filter preferred") in individuals with contraindications to anticoagulation. If the contraindication to prophylactic or therapeutic anticoagulation treatment persists or DVT is likely to recur, the algorithm recommends to "re-evaluate regularly for change in status." If the contraindication does not persist and is not likely to recur, the recommendation is for anticoagulation and filter removal. In 2020, three additional absolute contraindications were added. Two of these, neuraxial anesthesia/lumbar puncture and interventional spine and pain procedures had previously been considered relative contraindications and indwelling neuraxial catheters was newly added to the guideline. The changes were based on recommendations from anesthesia specialty societies and an FDA safety announcement (2013) with recommendations regarding the timing of spinal catheter placement and removal in individuals taking anticoagulant medications.

Contraindications to therapeutic anticoagulation are the following:

Absolute:

- Active bleeding (major): more than 2 units transfused, a decrease in hemoglobin by ≥ 2 g/dl, or intracranial or intraspinal bleeding
- Indwelling neuraxial catheters
- Neuraxial anesthesia/lumbar puncture
- Interventional spine and pain procedures

Relative:

- Chronic, clinically significant measurable bleeding > 48 hrs
- Thrombocytopenia (platelets $< 30,000$ - $50,000$ /mcL or clinical judgement)
- Underlying hemorrhagic coagulopathy or known bleeding disorder in the absence of replacement therapy
- Severe platelet dysfunction
- Recent major operation at high risk for bleeding
- High risk for falls (head trauma)
- CNS metastases
- Long-term antiplatelet therapy.

The NCCN guideline (V1. 2022) includes a category 2A recommendation for treatment of acute PE when the individual has a contraindication to anticoagulation stating, "Consider IVC filter (retrievable filter preferred) \pm embolectomy." The guideline also states that permanent filters should be considered only in "rare situations in which patients have permanent contraindications to anticoagulation or chronic comorbidities that preclude the use of anticoagulants."

The NCCN guideline (V1. 2022) includes a category 2A recommendation to "consider IVC filter (retrievable filter preferred) if venous thromboembolism (eg, lower-extremity DVT \pm PE) occurred within 1 month of surgery" or "postoperative anticoagulation based on bleeding risk." A perioperative thromboembolism risk assessment evaluates if the individual is at low, moderate, or high risk for bleeding when considering IVC filter placement.

Complications of VC Filter Placement and Removal

In a systematic review of the literature, Angel and colleagues (2011) reported an estimated 1.3% incidence of PE following retrievable IVC filter placement. Complications related to IVC filters include those associated with filter placement, such as bleeding or infection at the puncture site, allergic reaction to contrast or other medications used during placement, malposition of the filter, pneumothorax, air embolism, inadvertent carotid artery puncture, or other technical issues such as, guidewire entrapment within the filter.

Postprocedure complications of IVC placement include those at the access site (such as, acute venous thrombosis, hematoma, or arteriovenous fistula), and longer-term complications, such as filter erosion, migration or embolization, caval perforation, chronic thrombosis, recurrent thromboembolism, or consequences of filter retrieval (Wu, 2014).

Liu and colleagues (2021) performed a systematic review to identify RCTs for inclusion in their meta-analysis. The primary outcome was mortality related to PE. The secondary outcomes were overall mortality, PE, DVT and major bleeding. The review included seven articles and 1274 adult individuals. There were 638 individuals who received an IVC filter as an intervention who were compared to 636 individuals in the control group who did not receive an IVC filter as a medical management strategy. The authors found no

significant difference in mortality rates related to PE between the IVC filter and control groups within 3 months (risk difference, -0.01; 95% CI, -0.03 to 0.00; $p=0.11$) nor during the follow-up timeframe. The new occurrence of PE within 3 months and during the follow-up period was lower in the IVC filter group than in the control group (0.81% vs 5.98%; risk ratio, 0.17; 95% CI, 0.04-0.65; $p=0.01$; and 3.2% vs 7.79%; risk ratio, 0.42; 95% CI, 0.25-0.71; $p=0.001$). The researchers also indicated there were no significant differences in the rates of new occurrence of DVT, major bleeding and mortality during the entire follow-up period between the two groups ($p>0.05$). It was concluded that the researchers found insufficient evidence to state that the use of IVC filters can reduce mortality. However, as noted previously, their results indicate IVC filters can decrease the new occurrence of PE without increasing DVT or major bleeding.

Definitions

Absolute contraindication: A condition exists for not performing a particular diagnostic or therapeutic procedure that is so compelling that performing the particular treatment or procedure could result in a life-threatening situation and is absolutely inadvisable without exception or qualification (that is, must be avoided).

Anticoagulation: The process of hindering or reducing the ability of the blood to clot; the use of an anticoagulant drug to prevent the formation of blood clots.

Anticoagulants/anticoagulant therapy: Drugs used to reduce the ability of the blood to clot. Different types of anticoagulant therapy, each with a different mechanism of action used to treat conditions with a high risk of forming blood clots, include the following (by drug class):

- coumarins (warfarin);
- factor Xa inhibitors (including apixaban, betrixaban, edoxaban, fondaparinux, and rivaroxaban);
- low molecular weight heparins (LMWHs) (including dalteparin, enoxaparin, and tinzaparin); and,
- thrombin inhibitors (including argatroban, bivalirudin, dabigatran etexilate mesylate, and desirudin).

Deep vein thrombosis (DVT): A blood clot that forms in a vein deep in the body.

Inferior vena cava (IVC): The largest vein in the human body formed by the union of the two common iliac veins at the level of the fifth lumbar vertebra that returns blood to the right atrium of the heart from below the diaphragm.

IVC filter: A small device that traps large clot fragments and prevents them from traveling through the vena cava vein to the heart and lungs.

Permanent IVC filter placement: Permanent placement is deployment in those situations in which lifelong protection against thromboembolic episodes is needed (Caplin, 2011).

Pulmonary embolus/embolism (PE): An obstruction of a pulmonary artery (blood vessel in the lungs) or one of its branches, usually due to a blood clot that develops in a vein of the leg or pelvis and travels to the lungs. A PE is marked by labored breathing, chest pain, fainting, rapid heart rate, cyanosis, shock, and sometimes death. A pulmonary embolus is most often caused by a blood clot that develops in a vein outside the lungs.

Relative contraindication: A condition that makes a particular treatment or procedure possibly inadvisable unless the treatment or procedure is absolutely necessary. Consideration is given to perform the treatment or procedure if the benefits outweigh the risks.

Temporary IVC filter placement: Temporary placement is deployment in those situations in which time-limited protection against thromboembolic episodes is needed (Caplin, 2011).

Thrombus: A clot of blood formed within a blood vessel that remains attached to its place of origin.

Unprovoked DVT or PE: A DVT or PE associated with no apparent clinical risk factors.

Venous thromboembolism (VTE): A blood clot that forms in a vein and migrates (travels) to another location.

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Index

Vena cava filter
Inferior vena cava

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

| Status | Date | Action |
|----------|------------|---|
| Revised | 05/11/2023 | Medical Policy & Technology Assessment Committee (MPTAC) review. Revised MN section with minor text update. Updated References and Websites sections. |
| | 07/11/2022 | Updated Coding section to correct diagnosis codes for other mechanical complication to T82.595A-T82.595S. |
| Reviewed | 05/12/2022 | MPTAC review. Updated Discussion/General Information, References and Websites sections. |
| Revised | 05/13/2021 | MPTAC review. Removed major trauma indication from medically necessary statement. Reformatted 'not medically necessary' statement. Added "severe trauma without documented venous thromboembolism" and "cancer and recurrent venous thromboembolism, despite anticoagulation treatment" to the 'not medically necessary' statement. Updated Discussion/General Information, Coding, and References sections. |
| Revised | 12/16/2020 | Corrected diagnosis code T82.535A to T82.959A. |
| | 08/13/2020 | MPTAC review. In MN statement, regarding list of contraindications to anticoagulation, changed "including" to "including but not limited to". Updated Discussion/General Information and References sections. Reformatted Coding section; added diagnosis codes. |
| Reviewed | 08/22/2019 | MPTAC review. Updated Discussion/General Information and References sections. |
| Reviewed | 09/13/2018 | MPTAC review. Updated Discussion/General Information and References sections. |
| Revised | 11/02/2017 | MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Clarified NMN statement for prophylactic use of a vena cava filter, adding "...and for all other conditions including, but not limited to, prevention of venous thromboembolism in individuals undergoing bariatric surgery." Updated References, Websites for Additional Information, and Index sections. |
| New | 09/13/2017 | MPTAC review. Initial document development. |

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

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