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## Clinical Appropriateness Guidelines

# Vascular Interventions

# Appropriate Use Criteria: Vascular Embolization & Occlusion Procedures

### Proprietary

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# Table of Contents

Table of Contents .....	2
Description and Application of the Guidelines .....	3
General Clinical Guideline .....	4
Clinical Appropriateness Framework .....	4
Simultaneous Ordering of Multiple Diagnostic or Therapeutic Interventions .....	4
Repeat Diagnostic Intervention .....	4
Repeat Therapeutic Intervention .....	5
Vascular Embolization & Occlusion Procedures .....	6
General Information/Overview .....	6
Clinical Indications .....	6
Arterial Procedures .....	6
Venous Procedures .....	8
References .....	9
Codes .....	11
History .....	12

## Description and Application of the Guidelines

The Carelon Clinical Appropriateness Guidelines (hereinafter “the Carelon Clinical Appropriateness Guidelines” or the “Guidelines”) are designed to assist providers in making the most appropriate treatment decision for a specific clinical condition for an individual. The Guidelines establish objective and evidence-based criteria for medical necessity determinations, where possible, that can be used in support of the following:

- To establish criteria for when services are medically necessary
- To assist the practitioner as an educational tool
- To encourage standardization of medical practice patterns
- To curtail the performance of inappropriate and/or duplicate services
- To address patient safety concerns
- To enhance the quality of health care
- To promote the most efficient and cost-effective use of services

The Carelon guideline development process complies with applicable accreditation and legal standards, including the requirement that the Guidelines be developed with involvement from appropriate providers with current clinical expertise relevant to the Guidelines under review and be based on the most up-to-date clinical principles and best practices. Resources reviewed include widely used treatment guidelines, randomized controlled trials or prospective cohort studies, and large systematic reviews or meta-analyses. Carelon reviews all of its Guidelines at least annually.

Carelon makes its Guidelines publicly available on its website. Copies of the Guidelines are also available upon oral or written request. Additional details, such as summaries of evidence, a list of the sources of evidence, and an explanation of the rationale that supports the adoption of the Guidelines, are included in each guideline document.

Although the Guidelines are publicly available, Carelon considers the Guidelines to be important, proprietary information of Carelon, which cannot be sold, assigned, leased, licensed, reproduced or distributed without the written consent of Carelon.

Carelon applies objective and evidence-based criteria, and takes individual circumstances and the local delivery system into account when determining the medical appropriateness of health care services. The Carelon Guidelines are just guidelines for the provision of specialty health services. These criteria are designed to guide both providers and reviewers to the most appropriate services based on a patient’s unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice should be used when applying the Guidelines. Guideline determinations are made based on the information provided at the time of the request. It is expected that medical necessity decisions may change as new information is provided or based on unique aspects of the patient’s condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient and for justifying and demonstrating the existence of medical necessity for the requested service. The Guidelines are not a substitute for the experience and judgment of a physician or other health care professionals. Any clinician seeking to apply or consult the Guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient’s care or treatment.

The Guidelines do not address coverage, benefit or other plan specific issues. Applicable federal and state coverage mandates take precedence over these clinical guidelines, and in the case of reviews for Medicare Advantage Plans, the Guidelines are only applied where there are not fully established CMS criteria. If requested by a health plan, Carelon will review requests based on health plan medical policy/guidelines in lieu of the Carelon Guidelines. Pharmaceuticals, radiotracers, or medical devices used in any of the diagnostic or therapeutic interventions listed in the Guidelines must be FDA approved or conditionally approved for the intended use. However, use of an FDA approved or conditionally approved product does not constitute medical necessity or guarantee reimbursement by the respective health plan.

The Guidelines may also be used by the health plan or by Carelon for purposes of provider education, or to review the medical necessity of services by any provider who has been notified of the need for medical necessity review, due to billing practices or claims that are not consistent with other providers in terms of frequency or some other manner.

## General Clinical Guideline

### Clinical Appropriateness Framework

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Critical to any finding of clinical appropriateness under the guidelines for a specific diagnostic or therapeutic intervention are the following elements:

- Prior to any intervention, it is essential that the clinician confirm the diagnosis or establish its pretest likelihood based on a complete evaluation of the patient. This includes a history and physical examination and, where applicable, a review of relevant laboratory studies, diagnostic testing, and response to prior therapeutic intervention.
- The anticipated benefit of the recommended intervention should outweigh any potential harms that may result (net benefit).
- Widely used treatment guidelines and/or current clinical literature and/or standards of medical practice should support that the recommended intervention offers the greatest net benefit among competing alternatives.
- There exists a reasonable likelihood that the intervention will change management and/or lead to an improved outcome for the patient.

Providers may be required to submit clinical documentation in support of a request for services. Such documentation must a) accurately reflect the clinical situation at the time of the requested service, and b) sufficiently document the ordering provider's clinical intent.

If these elements are not established with respect to a given request, the determination of appropriateness will most likely require a peer-to-peer conversation to understand the individual and unique facts that would supersede the requirements set forth above. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account.

### Simultaneous Ordering of Multiple Diagnostic or Therapeutic Interventions

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Requests for multiple diagnostic or therapeutic interventions at the same time will often require a peer-to-peer conversation to understand the individual circumstances that support the medical necessity of performing all interventions simultaneously. This is based on the fact that appropriateness of additional intervention is often dependent on the outcome of the initial intervention.

Additionally, either of the following may apply:

- Current literature and/or standards of medical practice support that one of the requested diagnostic or therapeutic interventions is more appropriate in the clinical situation presented; or
- One of the diagnostic or therapeutic interventions requested is more likely to improve patient outcomes based on current literature and/or standards of medical practice.

### Repeat Diagnostic Intervention

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In general, repeated testing of the same anatomic location for the same indication should be limited to evaluation following an intervention, or when there is a change in clinical status such that additional testing is required to determine next steps in management. At times, it may be necessary to repeat a test using different techniques or protocols to clarify a finding or result of the original study.

Repeated testing for the same indication using the same or similar technology may be subject to additional review or require peer-to-peer conversation in the following scenarios:

- Repeated diagnostic testing at the same facility due to technical issues
- Repeated diagnostic testing requested at a different facility due to provider preference or quality concerns
- Repeated diagnostic testing of the same anatomic area based on persistent symptoms with no clinical change, treatment, or intervention since the previous study
- Repeated diagnostic testing of the same anatomic area by different providers for the same member over a short period of time

## **Repeat Therapeutic Intervention**

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In general, repeated therapeutic intervention in the same anatomic area is considered appropriate when the prior intervention proved effective or beneficial and the expected duration of relief has lapsed. A repeat intervention requested prior to the expected duration of relief is not appropriate unless it can be confirmed that the prior intervention was never administered.

# Vascular Embolization & Occlusion Procedures

## General Information/Overview

### Scope

These guidelines address Vascular Embolization & Occlusion Procedures in both adult and pediatric populations. For interpretation of the Guidelines, and where not otherwise noted, “adult” refers to persons aged 19 and older, and “pediatric” refers to persons aged 18 and younger. Where separate indications exist, they are specified as **Adult** or **Pediatric**. Where not specified, indications and prerequisite information apply to persons of all ages.

See the Coding section for a list of modalities included in these guidelines.

## Clinical Indications

The following section includes indications for which the specified vascular interventions are considered medically necessary, along with prerequisite information and supporting evidence where available. Indications, diagnoses, or procedures not specifically addressed are considered not medically necessary.

### Arterial Procedures

#### Prostate artery embolization

Prostate artery embolization is considered medically necessary in **EITHER** of the following scenarios:

- Benign prostatic hypertrophy in patients who are not surgical candidates and who have moderate to severe lower urinary tract symptoms
- Hematuria of prostatic origin

#### Splenic artery embolization

Partial splenic artery embolization is considered medically necessary in patients with gastric variceal bleeding and evidence of chronic splenic vein occlusion on imaging.

#### Treatment of primary or metastatic liver malignancy

*Includes transarterial embolization (TAE), transarterial chemoembolization (TACE) and selective internal radioembolization (SIRT)/transarterial radioembolization (TARE) procedures*

Transarterial embolization\* is considered medically necessary as treatment in **EITHER** of the following scenarios:

- Primary hepatocellular carcinoma or cholangiocarcinoma in **ANY** of the following scenarios:
  - Unresectable disease when **ALL** of the following are met:
    - Nodule(s) that are unresectable due to size (> 4 cm), location (adjacent to blood vessels), or multiplicity
    - Minimal or no extrahepatic disease
    - Preserved liver function (Childs-Pugh Class A or B)
  - As a bridge to liver transplant or when such treatment may allow a patient to be downstaged to become transplant eligible

- Treatment of liver-related symptoms due to tumor bulk
- Liver metastases in **ANY** of the following scenarios:
  - Liver-only or liver-predominant metastases from neuroendocrine tumor or uveal melanoma
  - As secondary treatment of chemotherapy resistant or refractory colorectal cancer with liver dominant metastases
  - Limited progressive hepatic metastatic disease unresponsive to systemic therapy
  - Treatment of liver-related symptoms due to tumor bulk

*\*TACE using drug-eluting beads (DEB-TACE) is not indicated.*

### Rationale

Evidence-based guidelines support the use of transarterial embolization procedures for primary and metastatic liver malignancies that may not be resectable, as a bridge to liver transplantation, and for palliation. For the indications above, evidence-based guidelines support the use of transarterial embolization (TAE), transarterial chemoembolization (TACE) and transarterial radioembolization (TARE)/selective internal radiation therapy (SIRT). Other techniques, including drug-eluting beads (DEB-TACE), are not generally recommended by guidelines.

### Treatment of renal tumors

Arterial embolization is considered medically necessary in **EITHER** of the following scenarios:

- Palliative treatment of renal cell carcinoma in patients with local symptoms (such as intractable hematuria) when unable to undergo nephrectomy.
- Treatment of renal angiomyolipoma (AML) as an alternative to resection or for acute hemorrhage

### Uterine artery embolization (UAE)

Transcatheter uterine artery embolization is considered medically necessary for treatment of uterine fibroids for excessive bleeding or symptoms of pelvic discomfort\*

*\*Symptoms may include severe pain, chronic lower abdominal pain, low back pressure, or bladder pressure with urinary frequency not due to urinary tract infection*

### Rationale

Multiple evidence-based guidelines support the use of uterine artery embolization for the treatment of uterine fibroids, with evidence showing reduction in bleeding, significant symptom relief and improved quality of life. Patient satisfaction rates 2-5 years after treatment are reported to be similar when comparing UAE, myomectomy, and hysterectomy, though the reintervention rate is higher with UAE compared to myomectomy and hysterectomy. The data comparing reproductive outcomes between UAE and myomectomy is limited, and results from the available studies have been conflicting. A 2021 ACOG Practice Bulletin states, "Uterine artery embolization (UAE) is recommended as an interventional procedure for the treatment of uterine leiomyomas in patients who desire uterine preservation and are counseled about the limited available data on reproductive outcomes.

Though the data are more limited regarding the use of UAE for pelvic hemorrhage from other causes, such as obstetric complications, an evidence-based guideline recommends attempting UAE before proceeding to more invasive interventions, noting lower morbidity and mortality rates compared to laparotomy and hysterectomy.

### Vascular aneurysm or malformation

Arterial embolization is considered medically necessary for treatment of arterial aneurysms or malformations (including but not limited to: congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, or pseudoaneurysms).

## Venous Procedures

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### Ovarian or internal iliac vein embolization

Iliac or ovarian vein embolization is considered medically necessary as a treatment for symptomatic pelvic congestion syndrome when imaging supports the presence of pelvic vein reflux.

#### Rationale

In the setting of pelvic congestion syndrome, ovarian vein embolization is frequently offered as treatment when there is documented periuterine venous dilation, and it has been shown to offer pain relief in a majority of cases. However, the available data is largely from case series including one meta-analysis of case series. There is little data regarding post-treatment impact on menstruation and fertility, and the data regarding effectiveness of repeat embolization procedures is contradictory. Though there are no randomized trials evaluating the efficacy of embolization, few other treatment options exist.

There is little data supporting the use of iliac or ovarian vein embolization in the setting of lower extremity varicose veins suspected to be of pelvic origin. An evidence-based guideline from the American College of Radiology states that, for treatment of pelvic-origin lower extremity varicose veins, ovarian vein embolization is “usually not appropriate,” and iliac vein embolization “may be appropriate.” However, the authors state that “there is no high-quality data demonstrating the value of pelvic embolization or iliac or renal vein stenting to improve pelvic origin varicose veins and their related symptoms,” and they also state, “No current prospective studies or randomized controlled trials demonstrating benefit of embolization for patients with pelvic-origin lower extremity varicose veins have been published. Current literature is limited to single-center case series which have failed to demonstrate significant improvement after pelvic venous embolization or stenting.”

### Portal vein embolization

Portal vein embolization is considered medically necessary when hepatic metastases cannot be optimally resected due to insufficient remnant liver volume.

### Testicular vein embolization (varicocele)

Testicular (spermatic) vein embolization is considered **NOT** medically necessary for treatment of varicocele.

#### Rationale

Embolization of testicular varicocele has been used as an alternative to surgical management. However, the evidence regarding the efficacy of this procedure is limited. A practice standard from the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) recommends treatment of varicoceles in specific scenarios: palpable varicocele, pain associated with varicocele, prevention or reversal of testicular atrophy in adolescent patients, documented infertility, abnormal semen parameters or sperm function test results, elevated sperm DNA fragmentation, or hypogonadism. These recommendations are not specific to embolization, however, and also include open, laparoscopic, and microscopic surgical approaches as well as sclerotherapy.

Regarding outcomes, treatment of varicocele leads to reduction in orchalgia and improved semen parameters (such as sperm concentration, motility, and morphology) in the majority of cases, with variable technical success depending on factors such as anatomy, vascular approach, and laterality (greater success with left-sided than with right-sided varicocele). However, the evidence is low or very low level, most based on retrospective studies with small study populations. There are few prospective studies evaluating the effectiveness of embolization, and those prospective studies are generally not randomized or blinded.

### Transhepatic variceal embolization

Percutaneous transhepatic embolization is considered medically necessary in **ANY** of the following scenarios:



- Acute variceal bleeding
- Cirrhosis with hepatocellular carcinoma
- Child-Pugh class C liver disease
- Branch portal vein thrombus

## Venous malformations, not otherwise specified

Venous embolization is considered medically necessary for treatment of venous malformations (*including but not limited to: congenital or acquired venous malformations and venous and capillary hemangiomas*).

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## Codes

The following code list is not meant to be all-inclusive. Authorization requirements will vary by health plan. Please consult the applicable health plan for guidance on specific procedure codes.

Specific CPT codes for services should be used when available. Nonspecific or not otherwise classified codes may be subject to additional documentation requirements and review.

### CPT/HCPCS

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37241	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; <b>venous</b> , other than hemorrhage (eg, congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles)
37242	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; <b>arterial</b> , other than hemorrhage or tumor (eg, congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms)

37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction
37244	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for <b>arterial or venous</b> hemorrhage or lymphatic extravasation

**ICD-10 Diagnosis**

Refer to the ICD-10 CM manual

## History

Status	Review Date	Effective Date	Action
Created	04/15/2024	11/01/2024	Original effective date. Independent Multispecialty Physician Panel (IMPP) review.