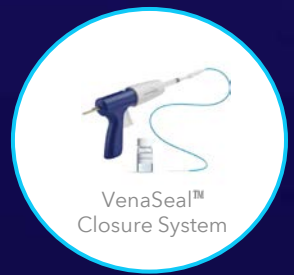


Medtronic

Engineering the extraordinary



VenaSeal™ Closure System

Prior authorization & appeal resources

Disclaimer

Medtronic provides this information for your convenience only. It does not constitute legal advice or a recommendation regarding clinical practice. Information provided is gathered from third-party sources and is subject to change without notice due to frequently changing laws, rules and regulations. The provider has the responsibility to determine medical necessity and to submit appropriate codes and charges for care provided. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other payers as to the correct form of billing or the amount that will be paid to providers of service. Please contact your Medicare contractor, other payers, reimbursement specialists and/or legal counsel for interpretation of coding, coverage and payment policies. This document provides assistance for FDA approved or cleared indications. Where reimbursement is sought for use of a product that may be inconsistent with, or not expressly specified in, the FDA cleared or approved labeling (e.g., instructions for use, operator's manual or package insert), consult with your billing advisors or payers on handling such billing issues. Some payers may have policies that make it inappropriate to submit claims for such items or related service. For more information, contact the Cardiovascular Health Economics, Policy & Reimbursement Team.

Resource table of contents

Overview

This document outlines resources available to support your efforts in obtaining coverage and prior authorization for the VenaSeal system for cyanoacrylate closure ablation (CAC)*. Click on the blue buttons below to access resources within this document as well as links to external resources.

Prior authorization & appeal resources

[Click here](#) Prior authorization & appeal guide

[Click here](#) Sample prior authorization letter

[Click here](#) Physician peer-to-peer guide

[Click here](#) Sample appeal letter - medical necessity denial

[Click here](#) Sample appeal letter - investigational denial

[Click here](#) Bibliography

Additional resources

[Click here](#) Product brochure

[Click here](#) Superficial venous coding guide

[Click here](#) Superficial venous interventions coding corner: diagnosis codes for varicose veins

[Click here](#) Superficial venous reimbursement guide

[Click here](#) Medicare prior authorization brief summary

[Click here](#) RF ablation and cyanoacrylate adhesive coverage matrix US

[Click here](#) VenaSeal™ closure system payer coverage list

*There are multiple different acronyms and synonyms used to describe cyanoacrylate closure ablation (CAC) in various guidelines, clinical studies, and payer coverage documents, including but not limited to cyanoacrylate glue ablation (CGA), cyanoacrylate glue occlusion, cyanoacrylate closure (CAC), cyanoacrylate adhesive closure (CAC), and cyanoacrylate adhesive ablation (CAA). These all are used to describe the cyanoacrylate closure ablation procedure.



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[Physician peer-to-peer guide](#) | [Sample appeal letter - medical necessity denial](#)
[Sample appeal letter - investigational denial](#) | [Bibliography](#) | [Additional resources](#)

Prior authorization & appeal guide

Overview

The information below depicts the general process for obtaining prior authorization from a payer. Prior authorization – sometimes called predetermination, preauthorization, precertification, clinical review, prior approval, preservice review, or advanced benefit notification – is a utilization management process used by payers to evaluate medical necessity and determine if certain products or services will be covered. This process requires providers to obtain advanced approval that medical necessity and coverage criteria have been met before services are provided. Prior authorization may take over 2 weeks, not including the appeal process. It is recommended providers consider this when scheduling the procedure.

Note: The information provided is for consideration only. The provider is responsible for determining medical necessity and submitting appropriate codes and charges for care provided. Please contact the payer for its prior authorization requirements and process. Use of this guide does not guarantee authorization or payment.

Payer types

Commercial

- Coverage and prior authorization requirements can vary by plan, and within a payer, based on an individual's policy.
- Prior authorization is recommended and may be required.

Traditional (Fee-For Service) Medicare (Parts A/B)

- Cyanoacrylate adhesive ablation (CAA) /VenaSeal closure system is addressed at the local level and every Medicare Administrative Contractor (MAC) has a Local Coverage Determination (LCD) extending positive coverage.¹ Please refer to the LCD or contact your local MAC for additional information. A map of the A/B MAC Jurisdictions can be found on the CMS [website](#).²
- Prior authorization is only required if performed in the hospital outpatient site of service.

Medicare Advantage (MA) (Part C)

- Provides the same coverage as traditional Medicare when there is an LCD/NCD in place.
- Prior authorization is recommended and may be required.

Medicaid

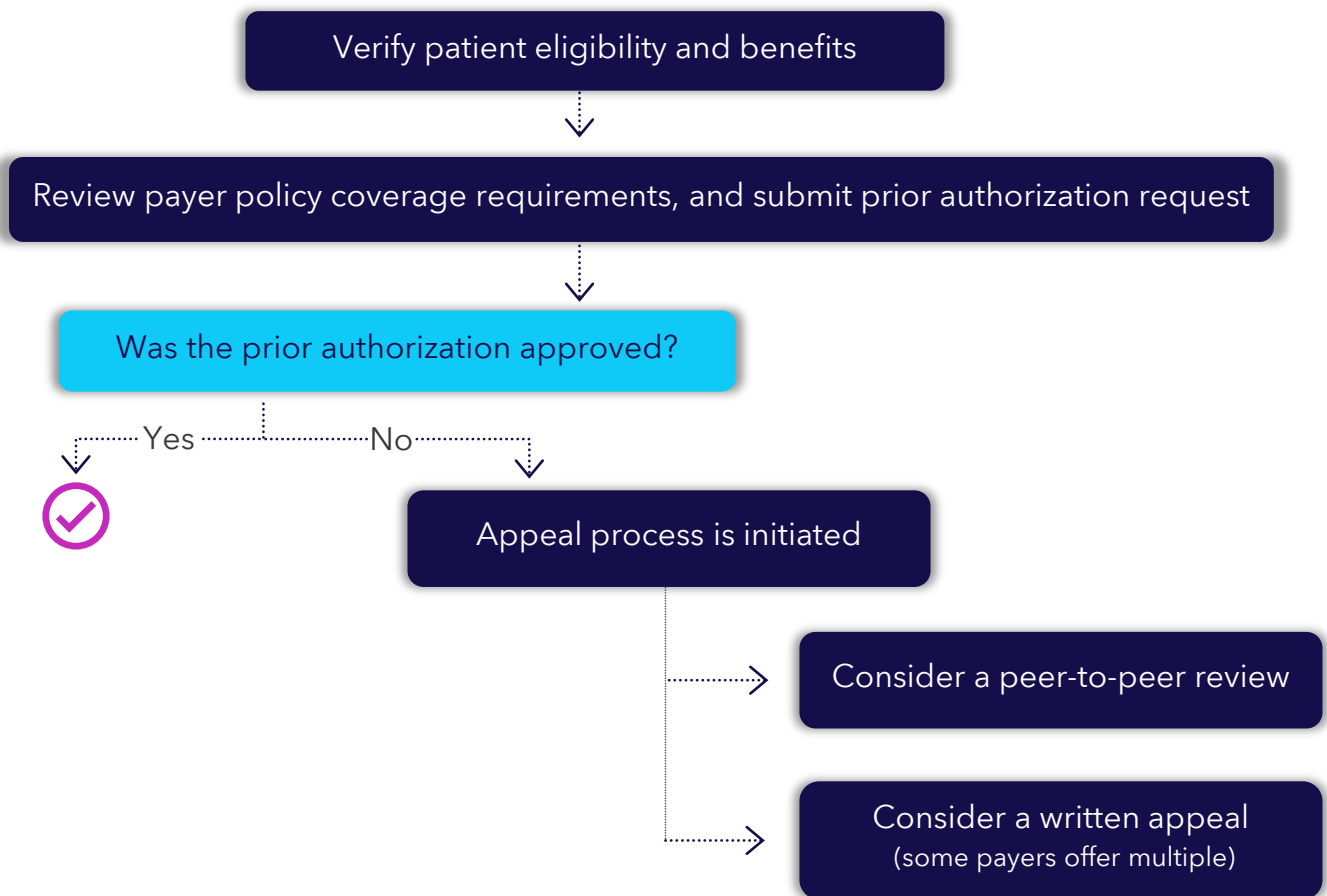
- Prior authorization is often required. Contact your state authority for instructions.



Considerations for obtaining a prior authorization

- **Coordination:** Identify a staff member to coordinate the prior authorization process (e.g., document payer interactions, track outcomes)
- **Clarification:** Determine prior authorization and coverage requirements before providing the service
- **Accuracy:** Ensure appropriate documentation is submitted and supports medical necessity and coverage criteria. Please refer to the payer's coverage policy.
- **Attention:** Regularly follow up with the payer to ensure a timely determination
- **Education:** If the prior authorization is denied, request the denial letter to determine the payer's rationale and appeal process
- **Escalation:** Inquire about a peer-to-peer review. Please refer to the [Physician Peer-to-Peer Guide](#).
- **Preparation:** If appealing, be prepared with documentation addressing the denial reason. Please refer to the [Sample Appeal Letters](#).

Prior authorization process flow chart*



*The process outlined above is generally for non-traditional Medicare payers (e.g., Commercial/Private, Medicare Advantage). Please contact the patient's payer for exact prior authorization steps.



Steps in the prior authorization process:

Step 1: Collect information

- Patient's name, date of birth, and identification number
 - Proceduralist's name and NPI
 - Name, address, and NPI of the facility where the procedure will take place (site of service)
 - Date of service (requesting a date range allows flexibility in scheduling and may prevent the need to resubmit your prior authorization request should a procedure be rescheduled). Please note: If prior authorization is approved, but the procedure is not performed within the date range requested, your claim may be denied.
 - Diagnosis, procedure, and place of service codes and descriptions
-

Step 2: Contact the payer

- **Verify patient eligibility and benefits for varicose vein treatment**
 - Inquire about a coverage policy for the procedure; many payers have a coverage policy with medical necessity requirements. If the payer has a noncoverage policy or is silent - there is not a policy that includes or excludes coverage for cyanoacrylate adhesive ablation/VenaSeal system - prior authorization is strongly recommended and allows providers to request a coverage exception based on the patient's clinical need.
 - Determine payer requirements for prior authorization. If prior authorization is not required, inquire if a predetermination or courtesy review is available. If no, document the date of your call, who you spoke with, and call reference number if available. **Please note there is a high likelihood of a claim denial if a pre-service review is not performed and there is a non-coverage policy.**
-

Step 3: Submit the request

- Determine the payer's prior authorization submission method: fax, phone, provider portal, email, or mail. Track submission method for future prior authorization requests.
- Gather and submit all supporting materials such as the information in Step 1, any payer required prior authorization forms, and supporting medical documentation (e.g., prescription, letter of medical necessity, medical records.)





Step 4: Follow-up

- Contact the payer within a few days of submission to verify receipt of the prior authorization request. If available, obtain the pending prior authorization number. Continue to follow up routinely until a determination has been made.
 - Prior authorization can take over 2 weeks, not including the appeal process.
 - Document payer interactions and track outcomes and time to determination.
-

Step 5: Verify outcome & eligibility

- If the prior authorization is approved, obtain the prior authorization number and request the approval letter. Re-verify the patient's eligibility to ensure they are still covered.
 - If the prior authorization is denied, request the denial letter to determine the payer's rationale and appeal process. Inquire about a peer-to-peer option. **Only continue to the next step if the prior authorization is denied.**
-

Step 6: Peer-to-peer

- **If the prior authorization is denied, the payer may allow a peer-to-peer review. Please contact the payer to inquire about this option.**
- Generally, this must be requested within a few hours to days upon notification of a denied prior authorization, and in some cases, could result in approval.



Step 7: Appeal

- Review the denial letter for the payer’s rationale and information regarding their appeal process. Of note, some payers may offer a reconsideration option prior to a formal appeal.
- Prepare an appeal, addressing the denial reason and including any new supporting medical documentation. If requesting a reconsideration, new information is typically required.
- Submit the appeal within the timeframe listed in the denial letter. Time frames can vary based on the payer; generally: 180 days for Commercial payers, 60 days for Medicare Advantage payers, and 30-45 days for Medicaid payers. Appeal determinations can take up to 30+ days.
- **In many cases, there is only one first level appeal available.** This can be submitted by the provider or patient. Patients may contact Member Services at the phone number on the back of their insurance card or their employer for assistance.

Step 8: Subsequent appeals

- **The appeal denial letter will provide information on additional appeal rights.**
- Generally, Commercial payers offer a second appeal (within 60 days) followed by an external review (within 120 days). An external review, also referred to as an independent medical review, is a final appeal submitted to a third-party review organization.
- For Medicare Advantage plans, the first appeal will automatically be sent to an Independent Review Entity (IRE) for a second appeal; providers can submit additional information to the IRE within 10 days.³ If the second appeal is denied, you may request review by the Office of Medicare Hearing and Appeals.³ This will involve a hearing before an Administrative Law Judge. For additional appeal rights, please contact the payer or the Centers for Medicare & Medicaid Services (CMS).³

References

¹Centers for Medicare & Medicaid Services. MCD Search. www.cms.gov.

<https://www.cms.gov/medicare-coverage-database/search.aspx>

²Centers for Medicare & Medicaid Services. Who are the MACs | CMS. www.cms.gov. Accessed July 5, 2024. <https://www.cms.gov/medicare/medicare-contracting/medicare-administrative-contractors/who-are-the-macs#MapsandLists>

³Medicare. Medicare.gov: the official U.S. government site for Medicare | Medicare. Medicare.gov. Published 2023. <https://www.medicare.gov/>



Sample prior authorization letter

Overview

This sample letter of medical necessity is to assist providers in obtaining prior authorization for the VenaSeal™ closure system for cyanoacrylate adhesive ablation and must be customized to the patient and payer. It is for your customization and may not include all the information necessary to support your request. The requesting provider is responsible for ensuring accuracy and adequacy of all information provided. Use of this letter does not guarantee authorization or payment.

Instructions

- Please do not include this instruction page to avoid misinterpretation of your prior authorization request as a form letter.
- It is recommended that providers use their business letterhead as appropriate.
- Please customize the sections in **red text** using information pertinent to yourself, your patient, and their condition/procedure. The remaining letter content can also be edited.
- This letter is not intended to replace any professional judgement; it is merely to assist with the prior authorization request. Providers are encouraged to include their professional expertise and experience with this procedure.
- It is important to contact the patient's insurance for the prior authorization timeline, submission process, and requirements. Additionally, please refer to the payer's policy for coverage and medical necessity criteria related to the procedure.

[Click here](#)

To open the sample prior authorization letter in Microsoft Word



Provider Letterhead – Please include organization name and address

Date

Payer Name

ATTN: Utilization Management/Prior Authorization Dept.

RE: **Prior authorization for VenaSeal™ closure system**

Patient name: Patient name

Date of birth: Date of birth

Policy ID number: Policy ID number

Diagnosis code(s): Diagnosis code(s)

Procedure code(s): Procedure code(s)

Date(s) of service: Date(s) of service

Place of service: Please of service

To Whom It May Concern,

On behalf of my patient, **patient name**, I am writing to request prior authorization for the Medtronic VenaSeal closure system for cyanoacrylate adhesive ablation, a procedure that I have deemed medically necessary over alternative varicose vein treatments.

The VenaSeal procedure is a minimally invasive nonthermal, nonsclerosant treatment for vein disease and varicose veins. It was granted premarket approval by the FDA in February 2015 and is indicated for use in the permanent closure of lower extremity superficial truncal veins, such as the great saphenous vein (GSV), through endovascular embolization with coaptation. The VenaSeal system is intended for use in adults with clinically symptomatic venous reflux as diagnosed by duplex ultrasound.

Explain the clinical rationale leading to the decision to recommend cyanoacrylate adhesive ablation/VenaSeal system and importantly, how the patient meets the payer's medical necessity criteria (refer to applicable varicose vein coverage policy). You may require one or more paragraphs to address the following:

- Patient's medical history
 - Diagnosis, start of diagnosis, and any diagnostic testing (e.g., duplex ultrasound with vein size)
 - Clinical presentation: symptoms (e.g., pedal pulse findings, skin changes, ulcers, bulging varicosities, swelling/edema), severity (e.g., CEAP classification), impact on quality of life and activities of daily living
- Relevant history (e.g., ulcers, DVT, cellulitis, other venous procedures or studies), risk factors, comorbidities
- Previous conservative treatments directed at addressing and/or managing the patient's condition (e.g., compression, exercise, elevation, NSAIDs), including duration of use and outcomes or limitations
- Plan of care including indication for the VenaSeal procedure and why alternative treatments are not recommended

In closing, I have determined the VenaSeal system for cyanoacrylate adhesive ablation is medically necessary for my patient and provided the above and enclosed information to support this. As such, I respectfully request approval for this procedure and reimbursement of all associated charges. If you have any questions, please contact me at **phone number**. Thank you for your review.

Sincerely,

Provider name and NPI/Tax ID

Enclosed: List of enclosures (e.g., prescription, history and physical, office visit notes, ultrasound report, any other relevant information you believe would make a persuasive argument for coverage such as clinical evidence)

Physician peer-to-peer guide

Overview

A peer-to-peer (P2P) review provides physicians the opportunity to discuss a denied prior authorization with the insurance company's Medical Director. This guide is intended to support P2P discussions for the VenaSeal closure system for cyanoacrylate adhesive ablation (CAA). **Use of this guide does not guarantee authorization or payment.**

Considerations:

- A P2P review is a scheduled phone call, typically brief, that must be arranged by the requesting physician or designated person from the requesting physician's office within the timeframe set by the payer. **Many payers require the call to be completed within 24-48 hours following a denied prior authorization.**
- A P2P review should occur prior to submitting a written appeal (or in accordance with the payer's peer-to-peer guidelines).
- A determination is usually made at the conclusion of the call. In some cases, a P2P review may result in an approved prior authorization.
- A P2P may not be available for all health plans.
- Supplemental resources, such as a [Bibliography](#), are available to support your P2P discussion.



Talking points

Before the call, take time to review the denial reason, payer's coverage policy, and patient documentation. The information provided below is for your consideration as you prepare for a P2P review of the VenaSeal closure system.

State your request and why you disagree with the denial

Even if the denial is a result of a payer's non-coverage policy, the goal of the P2P is to request a coverage exception for the VenaSeal system for cyanoacrylate adhesive ablation (CAA) based on medical necessity.

Describe the VenaSeal system as the Medical Director may not be familiar

The VenaSeal procedure is a minimally invasive nonthermal, nonsclerosant treatment for vein disease and varicose veins. It delivers a small amount of a specially formulated medical adhesive to seal - or close - the diseased vein, rerouting blood to nearby healthy veins and providing symptom relief.

The VenaSeal closure system was granted premarket approval by the FDA in February 2015.

The VenaSeal closure system (VenaSeal system) is indicated for use in the permanent closure of lower extremity superficial truncal veins, such as the great saphenous vein (GSV), through endovascular embolization with coaptation. The VenaSeal system is intended for use in adults with clinically symptomatic venous reflux as diagnosed by duplex ultrasound (DUS).

Explain the medical necessity of this therapy for your patient

Provide overview of the patient's condition:

- Diagnosis, date of diagnosis, any diagnostic testing (e.g., duplex ultrasound with vein size)
- Clinical presentation: symptoms (e.g., pedal pulse findings, skin changes, bulging varicosities, swelling/edema), severity (e.g., CEAP classification), impact on quality of life and activities of daily living, etc.

Discuss previous treatments (e.g., compression, exercise, elevation, NSAIDs) including duration of use and why these modalities failed to adequately manage the patient's symptoms

Describe reason for the procedure and why alternative varicose vein treatments are not recommended



Discuss the clinical risks and benefits/goals of the VenaSeal system for this patient

Risks (as discussed with the patient): Please refer to the [Instructions for Use](#) and [Brief Statement](#).

Benefits/Goals (as discussed with the patient):

- To offer a minimally invasive treatment option with no tumescent anesthesia or risk of thermal nerve injury^{1,2} and rapid return to normal activities^{3,4}
- To minimize pain, tenderness, and ecchymosis⁴ and improve quality of life⁵
- To provide lasting results, with high closure rate out to five years³

Risks and benefits of the therapy have been reviewed and discussed with the patient. After review, it has been decided that the benefits of the therapy outweigh the risks for this patient.

Share your experience with the VenaSeal system

Procedure volume and clinical outcomes for patients who receive this therapy

Describe any other key factors supporting your request

Leverage clinical evidence to substantiate the clinical benefit your patient may achieve with this therapy. Focus on guidelines, safety, efficacy, and patient selection.

Discuss payers that have covered the VenaSeal system for your patients.



References

- ¹ Proebstle T, Alm J, Dimitri S, et al. Three-year follow-up results of the prospective European Multicenter Cohort Study on Cyanoacrylate Embolization for treatment of refluxing great saphenous veins. *J Vasc Surg Venous Lymphat Disord*. March 2021;9(2):329-334.
- ² Almeida JI, Javier JJ, Mackay EG, Bautista C, Cher DJ, Proebstle TM. Thirty-sixth month follow-up of first-in-human use of cyanoacrylate adhesive for treatment of saphenous vein incompetence. *J Vasc Surg Venous Lymphat Disord*. September 2017;5(5):658-666.
- ³ Morrison N, Gibson K, McEnroe S, et al. Randomized trial comparing cyanoacrylate embolization and radiofrequency ablation for incompetent great saphenous veins (VeClose). *J Vasc Surg*. April 2015;61(4):985-994.
- ⁴ Gibson K, Ferris B. Cyanoacrylate closure of incompetent great, small and accessory saphenous veins without the use of post-procedure compression: Initial outcomes of a post-market evaluation of the VenaSeal System (the WAVES Study). *Vascular*. April 2017;25(2):149-156.
- ⁵ Morrison N, Gibson, Vasquez M, et al. VeClose trial 12-month outcomes of cyanoacrylate closure versus radiofrequency ablation for incompetent great saphenous veins. *J Vasc Surg*. 2017;5(3):321-330.



Sample appeal letter - medical necessity denial

Overview

This sample appeal letter is to assist providers in appealing a medical necessity denial for the VenaSeal™ closure system for cyanoacrylate adhesive ablation and must be customized to the patient and payer. It is for your consideration and may not include all the information necessary to support your request. The requesting provider is responsible for ensuring accuracy and adequacy of all information provided. Use of this letter does not guarantee authorization or payment.

Instructions

- Please do not include this instruction page to avoid misinterpretation of your appeal request as a form letter.
- It is recommended that providers use their business letterhead as appropriate.
- Please customize the sections in **red text** using information pertinent to yourself, your patient, and their condition/procedure. The remaining letter content can also be edited.
- This letter is not intended to replace any professional judgement; it is merely to assist with the appeal request. Providers are encouraged to include their professional expertise and experience with this procedure.
- It is important to review the payer's denial letter for appeal timeline, submission process, and requirements. Additionally, please refer to the payer's medical policy for coverage criteria related to the procedure.

[Click here](#)

To open the sample appeal letter in
Microsoft Word



Provider Letterhead – Please include organization name and address

Date

RE: **Appeal for VenaSeal™ closure system** – Prior authorization/reference number or Claim number (if available)

Patient name: **Patient name**

Diagnosis code(s): **Diagnosis code(s)**

Date of birth: **Date of birth**

Procedure code(s): **Procedure code(s)**

Policy ID number: **Policy ID number**

Date(s) of service: **Date(s) of service**

Dear **Payer Name**,

I am the treating physician for **patient name** and am writing to appeal the denial of the Medtronic VenaSeal closure system for cyanoacrylate adhesive ablation, a procedure that I have deemed medically necessary. The denial indicates this procedure is not medically necessary because **rationale from denial letter or Explanation of Benefits**. Additionally, I am requesting review of the denial and enclosed clinical documentation by a physician with similar medical specialty. **If appealing a claim denial, include details of any pre-procedure approval/confirmation of coverage (e.g., predetermination, prior authorization)**

The VenaSeal procedure is a minimally invasive nonthermal, nonsclerosant treatment for vein disease and varicose veins. It was granted premarket approval by the FDA in February 2015 and is indicated for use in the permanent closure of lower extremity superficial truncal veins, such as the great saphenous vein, through endovascular embolization with coaptation. The VenaSeal system is intended for use in adults with clinically symptomatic venous reflux as diagnosed by duplex ultrasound.

Describe how the patient meets the coverage criteria outlined in the payer's medical policy or the reason why an exception is needed based on the patient's unique clinical circumstance. This may include:

- **Diagnosis and start of diagnosis**
- **Relevant history (e.g., ulcers, DVT, cellulitis, other venous procedures or studies)**
- **Duplex ultrasound: date performed, incompetent vein (e.g., GSV, SSV), and findings (e.g., vein size, reflux duration)**
- **Clinical presentation**
 - **Symptoms (e.g., pedal pulse findings, skin changes, ulcers, bulging varicosities, swelling/edema) and severity (e.g., CEAP classification)**
 - **Impact on quality of life and activities of daily living**
- **Conservative treatments that have been tried (e.g., compression, exercise, elevation, NSAIDs), including duration of use and why these modalities failed to adequately manage the patient's symptoms**

In closing, I have determined the VenaSeal system is medically necessary for my patient and provided the above and enclosed information to support this. As such, I respectfully request reconsideration for coverage and reimbursement of all charges associated with the procedure. If you have any questions, please contact me at **phone number**. Thank you for your review.

Sincerely,

Provider name and NPI/Tax ID

Enclosed: List of enclosures (e.g., Denial letter or Explanation of Benefits, prescription, history and physical, office visit notes, ultrasound report, other relevant information you believe would make a persuasive argument for coverage)

Sample appeal letter - investigational denial

Overview

This sample appeal letter is to assist providers in appealing an investigational or experimental denial for the VenaSeal™ closure system for cyanoacrylate adhesive ablation and must be customized to the patient and payer. It is for your consideration and may not include all the information necessary to support your request. The requesting provider is responsible for ensuring accuracy and adequacy of all information provided. Use of this letter does not guarantee authorization or payment.

Instructions

- Please do not include this instruction page to avoid misinterpretation of your appeal request as a form letter.
- It is recommended that providers use their business letterhead as appropriate.
- Please customize the sections in **red text** using information pertinent to yourself, your patient, and their condition/procedure. The remaining letter content can also be edited.
- This letter is not intended to replace any professional judgement; it is merely to assist with the appeal request. Providers are encouraged to include their professional expertise and experience with this procedure.
- It is important to review the payer's denial letter for appeal timeline, submission process, and requirements.
- Supplemental resources are available to accompany your appeal request, such as a [Bibliography](#).

[Click here](#)

To open the sample appeal letter in
Microsoft Word



Provider Letterhead – Please include organization name and address

Date

RE: **Appeal for VenaSeal™ closure system – Prior authorization/reference number or Claim number (if available)**

Patient name: **Patient name**

Date of birth: **Date of birth**

Policy ID number: **Policy ID number**

Diagnosis code(s): **Diagnosis code(s)**

Procedure code(s): **Procedure code(s)**

Date(s) of service: **Date(s) of service**

Dear **Payer Name**,

I am the treating physician for **patient name** and am writing to appeal the denial of the Medtronic VenaSeal closure system for cyanoacrylate adhesive ablation, a procedure that I have deemed medically necessary. The denial indicates this procedure is considered investigational/experimental. Additionally, I am requesting review of the denial and enclosed clinical documentation by a physician with similar medical specialty. **If appealing a claim denial, include details of any pre-procedure approval/confirmation of coverage (e.g., predetermination, prior authorization)**

The VenaSeal procedure is a minimally invasive nonthermal, nonsclerosant treatment for vein disease and varicose veins. It was granted premarket approval by the FDA in February 2015 and is indicated for use in the permanent closure of lower extremity superficial truncal veins, such as the great saphenous vein, through endovascular embolization with coaptation. The VenaSeal system is intended for use in adults with clinically symptomatic venous reflux as diagnosed by duplex ultrasound. There is no risk of thermal nerve injury (Morrison et al., 2015), less pain and bruising than thermal treatment (Morrison et al., 2015; Proebstle et al., 2021), no tumescent anesthesia, rapid return to daily activities (Gibson et al., 2017), and no post procedure compression stockings (Proebstle et al., 2021; Almeida et al., 2017).

The 2022 and 2023 Society for Vascular Surgery, American Venous Forum, and American Vein and Lymphatic Society clinical practice guidelines for varicose veins support cyanoacrylate adhesive ablation as standard of care along with other vein treatments. The guidelines are based on systematic reviews, a randomized controlled trial with 5-year follow-up, and prospective and retrospective studies concluding cyanoacrylate is safe and effective for symptomatic varicose vein treatment. These studies demonstrate durable and complete vein closure, faster wound healing, decreased risk of recurrent vein incompetence, and overall improved symptoms and quality of life. Many payers, including Medicare **and any other payers that have covered the VenaSeal system for your patients**, have extended coverage for this procedure.

Address the denial reason and why you disagree (Please note: Even if the denial is a result of a payer's noncoverage policy, the goal for the appeal is to request a coverage exception based on the patient's clinical need), including:

- **Patient's relevant medical history**
 - **Diagnosis, date of diagnosis**
 - **Clinical presentation: symptoms, severity, impact on quality of life and activities of daily living**
 - **Previous conservative treatments tried and failed**
- **Clinical benefits/goals of VenaSeal for this patient**
- **Why alternative treatments are not recommended (e.g., inability to treat full length of refluxing vein – above and below the knee, risk of thermal nerve injury, patient is unable to use compression stockings post procedure)**
- **Your experience with VenaSeal (e.g., procedure volume, outcomes) and other key facts supporting your request (e.g., additional clinical studies)**

In closing, the VenaSeal system is not investigational or experimental. It has been well studied in peer-reviewed literature, determined by several specialty societies to be standard treatment for varicose veins, and subsequently covered by the majority of payers. I have provided information to support this is the best treatment option for my patient and respectfully request reconsideration of coverage and reimbursement. If you have questions, please contact me at **phone number**. Thank you for your review.

Sincerely,

Provider name and NPI/Tax ID

Enclosed: **List of enclosures (e.g., Denial letter or Explanation of Benefits, prescription, history and physical, office visit notes, ultrasound report, other relevant information you believe would make a persuasive argument for coverage)**

References

- Almeida JJ, Javier JJ, Mackay EG, Bautista C, Cher DJ, Proebstle TM. Thirty-sixth month follow-up of first-in-human use of cyanoacrylate adhesive for treatment of saphenous vein incompetence. *J Vasc Surg Venous Lymphat Disord*. September 2017;5(5):658-666.
- Gibson K, Ferris B. Cyanoacrylate closure of incompetent great, small and accessory saphenous veins without the use of post-procedure compression: Initial outcomes of a post-market evaluation of the VenaSeal System (the WAVES Study). *Vascular*. April 2017;25(2):149-156.
- Morrison N, Gibson K, McEnroe S, et al. Randomized trial comparing cyanoacrylate embolization and radiofrequency ablation for incompetent great saphenous veins (VeClose). *J Vasc Surg*. April 2015;61(4):985-994.
- Proebstle T, Alm J, Dimitri S, et al. Three-year follow-up results of the prospective European Multicenter Cohort Study on Cyanoacrylate Embolization for treatment of refluxing great saphenous veins. *J Vasc Surg Venous Lymphat Disord*. March 2021;9(2):329-334.

Bibliography

Overview

This bibliography includes articles that support the approved U.S. Food and Drug Administration indication for the VenaSeal™ system, and therefore deemed to be relevant to aid in the payer decision-making process. This includes clinical practice guidelines, systematic reviews and meta-analyses, randomized controlled trials, real-world evidence, and reviews by nationally recognized health care organizations. This list is current as of July 9, 2024, and is not exhaustive of all articles on the VenaSeal™ system. For safety information, please refer to the [Brief Statement](#).

Clinical Practice Guidelines

De Maeseneer MGD, Kakkos SK, Aherne T, et al. Editor's Choice - European Society for Vascular Surgery (ESVS) 2022 Clinical Practice Guidelines on the Management of Chronic Venous Disease of the Lower Limbs. *European Journal of Vascular and Endovascular Surgery*. 2022;63(2):184-267.

Gloviczki P, Lawrence PF, Wasan SM, et al. The 2023 Society for Vascular Surgery, American Venous Forum, and American Vein and Lymphatic Society Clinical Practice Guidelines for the Management of Varicose Veins of the Lower Extremities. Part II [published online ahead of print, 2023 Aug 29]. *J Vasc Surg Venous Lymphat Disord*. 2023;S2213-333X(23)00322-0. doi:10.1016/j.jvsv.2023.08.011

Gloviczki P, Lawrence PF, Suman MW, et al. The 2022 Society for Vascular Surgery, American Venous Forum, and American Vein and Lymphatic Society clinical practice guidelines for the management of varicose veins of the lower extremities. *J Vasc Surg Venous Lymphat Disord*. 2022. doi: <https://doi.org/10.1016/j.jvsv.2022.09.004>.

Utilization Management Care Guidelines/Criteria

InterQual Clinical Criteria. CP: Procedures - Endovenous Ablation, Lower Extremity Superficial Truncal or Perforator Vein. Mar. 2024 Release. Accessed via <https://prod.cue4.com/caas/review/subsetSelect> on June 28, 2024.

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Brief Statement

VenaSeal™ Closure System Brief Statement

Intended Use/Indications: The VenaSeal™ closure system (VenaSeal™ system) is indicated for use in the permanent closure of lower extremity superficial truncal veins, such as the great saphenous vein (GSV), through endovascular embolization with coaptation. The VenaSeal system is intended for use in adults with clinically symptomatic venous reflux as diagnosed by duplex ultrasound (DUS).

Contraindications: Separate use of the individual components of the VenaSeal closure system is contraindicated. These components must be used as a system. The use of the VenaSeal system is contraindicated when any of the following conditions exist previous hypersensitivity reactions to the VenaSeal™ adhesive or cyanoacrylates, acute superficial thrombophlebitis, thrombophlebitis migrans, acute sepsis.

Potential Adverse Effects of the Device on Health: The potential adverse effects (e.g., complications) associated with the use of the VenaSeal system include, but are not limited to, adverse reactions to a foreign body (including, but not limited to, nonspecific mild inflammation of the cutaneous and subcutaneous tissue), arteriovenous fistula, bleeding from the access site, deep vein thrombosis (DVT), edema in the treated leg, embolization, including pulmonary embolism (PE), hematoma, hyperpigmentation, hypersensitivity or allergic reactions to cyanoacrylates, such as urticaria, shortness of breath, and anaphylactic shock, infection at the access site, pain, paresthesia, phlebitis, superficial thrombophlebitis, urticaria, erythema, or ulceration may occur at the injection site, vascular rupture and perforation, visible scarring.

Warnings, precautions, and instructions for use can be found in the product labeling at <http://manuals.medtronic.com>.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.



Contact

For additional information, contact the Medtronic Reimbursement Customer Support team:



By email at

rs.cardiovascularhealtheconomics@medtronic.com



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