



SAMPLE LETTER OF MEDICAL NECESSITY TEMPLATE

To be considered for prior authorization by physicians

Instructions for completing the sample medical necessity letter:

1. Please customize the medical necessity letter template based on the medical appropriateness. Fields required for customization are in **RED**.
2. Letters of medical necessity are often key to requesting prior authorization of procedures.
3. After you have customized the letter, ***please make sure to delete*** any specific instructions for completion, disclaimers, Abbott logos, caution statement, tradeographs and document number that are seen throughout the letter so the health plan does not misinterpret the information.
4. For independent consideration and review; please make all changes that you believe appropriate, or disregard these suggestions in their entirety. The customer is ultimately responsible for the accuracy and completeness of all claims submitted to third-party payers. Please see the FDA-approved label for information relevant to any prescribing decisions.

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[Physician Letterhead]

[Date]

Attention: Prior Authorization Department

[Payer contact name]

[Payer contact title]

[Payer]

[Street address]

[City, State, zip code]

Re: Request for Prior Authorization of Transcatheter Patent Foramen Ovale (PFO) closure

Patient name: *[First and last name]*

Patient date of birth: *[XX/XX/XXXX]*

SS # *[XXX-XX-XXXX]*

Insurance ID # *[XXXXXXXXXXXXXXXXXX]*

Group # *[XXXXXXXXXX]*

Date of Service: *[XX/XX/XXXX]*

CPT[‡] Code:

[93580 – Percutaneous transcatheter closure of congenital interatrial communication (i.e., Fontan fenestration, atrial septal defect) with implant]

For physician and outpatient facility billing if billing Medicare or Medicare Advantage, the facility may also report:

[C1817 – Septal defect implant system, intracardiac]

Inpatient for all payers:

[02U53JZ – Supplement atrial septum with synthetic substitute, percutaneous approach]

Dear *[Payer contact name]*:

I am writing to request prior authorization of services I deem medically necessary for the above-referenced procedure. The service involves the implant of the Amplatzer™ PFO Occluder to be provided to *[patient's name]* on *[procedure date]* in the *[inpatient/outpatient]* setting.

According to a comprehensive neurological assessment, *[insert patients name]* this patient suffered from an ischemic stroke of undetermined etiology – the so called cryptogenic stroke. The diagnosis of cryptogenic ischemic stroke has been documented by the referring physician, and results of the following relevant tests are attached *[Specify all tests that apply]*

- Echocardiogram reports documenting diagnosis of Patent Foramen Ovale (PFO)
- Documentation of index cryptogenic ischemic stroke
- Test results for typical sources of cardioembolism as a cause for ischemic stroke
 - ECG results for rhythm disorders such as Atrial Fibrillation or Flutter
 - Echocardiogram reports for other cardiogenic sources of embolism
- Imaging of cerebral and extra-cerebral arteries for atherosclerotic causes of stroke
- Hematological evaluation for underlying hypercoagulable state
- ***[Additional examination and imaging as necessary]***

The secondary stroke prevention for this patient includes *[standard of care antithrombotic/specify]* medical treatment. However, the final results from the RESPECT trial have demonstrated that after long-term follow-up (~6 years); closure with the Amplatzer™ PFO Occluder was superior to the standard of care medical therapy alone in preventing recurrent ischemic stroke, reducing the hazard rate by nearly half. I believe that this patient will benefit from an additional preventative measure, such as an implantation of the Amplatzer™ PFO Occluder.

[Insert, if applicable] Moreover, this medical treatment cannot be *[effective / tolerated/adhered to]* by this patient for the following reason(s): *[insert clinical reasons why the medical treatment alone is no longer sufficient or advisable for this patient]*

[Or Insert, if applicable] Moreover, this medical treatment alone is not sufficient for this patient for the following reason(s): [insert clinical reasons why this is a high risk of recurrent stroke and why this patient will benefit from PFO closure]

The Amplatzer™ PFO Occluder is to be implanted at the location of the atrial septum to close a PFO by creating a barrier to right-to-left shunting. In some patients with cryptogenic ischemic stroke, the presence of a PFO raises the possibility that a thromboembolism from the venous circulation passed through the PFO into the arterial circulation (paradoxical thromboembolism) leading to an ischemic stroke. The Amplatzer™ PFO Occluder is indicated for percutaneous transcatheter closure of a patent foramen ovale (PFO) to reduce the risk of recurrent ischemic stroke in patients, predominantly between the ages of 18 and 60 years, who have had a cryptogenic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude known causes of ischemic stroke. I have also attached a copy of the FDA approval letter.

I believe that in this case the Amplatzer™ PFO Occluder implant is medically reasonable and necessary and as such this service should receive prior authorization of coverage and payment for related services.

Please let me know if I can provide any additional information, and thank you for your attention.

Sincerely,

[Physician's name and credentials]

[Title]

[Name of practice]

[Street address]

[City, State, zip code]

[Phone number]

Enclosures:

[Patient medical records/chart notes]

[FDA Approval letter – Amplatzer™ PFO Occluder]

[Clinical evidence summary]

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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SJM-HER-0119-0165 | Item approved for U.S. use only.

