PIPELINE™ FLEX EMBOLIZATION DEVICE
CODING AND REIMBURSEMENT GUIDE
The Pipeline™ Flex embolization device is a braided, multi-alloy cylindrical mesh indicated for the endovascular treatment of adults (age 22 and above) with large or giant wide-necked intracranial aneurysms in the internal carotid artery from the petrous to the superior hypophyseal segments. The Pipeline™ Flex device is intended to treat intracranial aneurysms by two mechanisms of action:

**FLOW DISRUPTION**
Placement of a Pipeline™ Flex device in the parent artery disrupts the pulsatile flow of blood from the parent artery into the intracranial aneurysm fundus. Stasis of blood in the intracranial aneurysm fundus leads to increased blood viscosity, which favors thrombosis. Formation of a blood clot relieves the aneurysm fundus walls from systematic blood pressure, minimizing the risk of spontaneous rupture.

**RE-ENDOTHELIALIZATION**
The Pipeline™ Flex device forms a scaffold upon which endothelial cells can grow. Full coverage of the implant, including over the neck of the intracranial aneurysm, seals the intracranial aneurysm fundus from the parent artery, minimizing the risk of spontaneous rupture as well as recanalization of the aneurysm. The device mesh forms a distinct but smooth border between parent artery and aneurysm fundus.

For Medicare patients, the procedure with the Pipeline™ Flex device is required to be performed in the hospital inpatient setting.
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The following information is calculated per the footnotes included and does not take into effect Medicare payment reductions resulting from sequestration associated with the Budget Control Act of 2011. Sequestration reductions went into effect on April 1, 2013.

For questions please contact us at neuro.us.reimbursement@medtronic.com

ICD-10-CM DIAGNOSIS CODES—effective October 1, 2017
ICD-10-CM diagnosis codes are used by both physicians and hospitals to report the indication for the procedure.

<table>
<thead>
<tr>
<th>CODE</th>
<th>CODE DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>I67.1</td>
<td>Cerebral aneurysm, nonruptured</td>
</tr>
<tr>
<td>Q28.3</td>
<td>Other malformations of cerebral vessels</td>
</tr>
</tbody>
</table>

ICD-10-PCS PROCEDURE CODES—effective October 1, 2017
ICD-10-PCS procedure codes are used by hospitals to report surgeries and procedures performed in the inpatient setting.

<table>
<thead>
<tr>
<th>CODE</th>
<th>CODE DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>03VG3DZ</td>
<td>Restriction of intracranial artery with intraluminal device, percutaneous approach</td>
</tr>
<tr>
<td>B31R1ZZ</td>
<td>Fluoroscopy of intracranial arteries using low osmolar contrast</td>
</tr>
<tr>
<td>B31RYY3</td>
<td>Fluoroscopy of intracranial arteries using other contrast</td>
</tr>
</tbody>
</table>

HCPCS DEVICE CODES
HCPCS device codes are assigned by the entity that purchased and supplied the device to the patient. In the case of Pipeline™ Flex, that is the hospital. However, hospitals assign HCPCS device codes only when the device is provided in the hospital outpatient setting. HCPCS device codes cannot be assigned or billed for procedures performed in the inpatient setting. If a hospital requires a HCPCS device code for an inpatient case for internal purposes only, such as for tracking, please refer to the HCPCS addendum for references.

DRG ASSIGNMENT FY2018 – effective October 1, 2017
Under Medicare’s MS-DRG methodology for hospital inpatient payment, each inpatient stay is assigned to one of about 750 diagnosis-related groups, based on the ICD-10 codes assigned to the diagnoses and procedures. Each MS-DRG has a relative weight that is then converted to a flat payment amount. Implanted devices are typically included in the flat payment and are not paid separately. Only one MS-DRG is assigned for each inpatient stay regardless of the number of procedures performed. MS-DRGs shown are those typically assigned to the following scenarios.
**PROCEDURE CODING AND PAYMENT**

Physicians use CPT® codes for all services. Under Medicare’s Resource-Related Value Scale (RBRVS) methodology for physician payment, each CPT® code is assigned a point value, the relative value unit (RVU), which is then flattened to a payment amount.

**CPT® CODES**[1] – effective January 1, 2018

<table>
<thead>
<tr>
<th>CODE</th>
<th>DESCRIPTION</th>
<th>CY2018 MEDICARE</th>
<th>CY2018 MEDICARE</th>
<th>REFERENCES</th>
</tr>
</thead>
<tbody>
<tr>
<td>61624</td>
<td>Transcatether permanent occlusion or embolization (e.g., for tumor destruction, to achieve hemostasis, to exclude vessel wall malformation, percutaneous, any method; central nervous system [intracranial, spinal cord])</td>
<td>$1,209</td>
<td>Yes</td>
<td>[5]</td>
</tr>
<tr>
<td>75894-26</td>
<td>Transcatether therapy; embolization, any method; radiological supervision and interpretation</td>
<td>$74</td>
<td>No</td>
<td>[7]</td>
</tr>
<tr>
<td>36224</td>
<td>Selective catheter placement, intracranial arterial embolization, with angiography of the intracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the extracranial carotid and cervical arterial system, when performed</td>
<td>$480</td>
<td>No</td>
<td>[9]</td>
</tr>
<tr>
<td>36226</td>
<td>Selective catheter placement, vertebral arterial embolization, with angiography of the vertebral circulation and all associated radiological supervision and interpretation</td>
<td>$370</td>
<td>No</td>
<td>[9]</td>
</tr>
<tr>
<td>36238</td>
<td>Selective catheter placement, each intracranial branch of the internal carotid or vertebral arteries, unilateral, with angiography of the selected vessel circulation and all associated radiological supervision and interpretation (e.g., middle cerebral artery, posterior inferior cerebellar artery)</td>
<td>$629</td>
<td>No</td>
<td>[9]</td>
</tr>
</tbody>
</table>

**PIVLINE® FLEX EMBOLIZATION PROCEDURE**[10,20]

1. **Physician**
   - Physicians use CPT® codes for all services.
   - Under Medicare’s Resource-Related Value Scale (RBRVS) methodology for physician payment, each CPT® code is assigned a point value, the relative value unit (RVU), which is then flattened to a payment amount.
   - **CPT® CODES**[1] – effective January 1, 2018
     - | CODE | DESCRIPTION | CY2018 MEDICARE | CY2018 MEDICARE |
     - | 61624 | Transcatether permanent occlusion or embolization (e.g., for tumor destruction, to achieve hemostasis, to exclude vessel wall malformation, percutaneous, any method; central nervous system [intracranial, spinal cord]) | $1,209 | Yes |
     - | 75894-26 | Transcatether therapy; embolization, any method; radiological supervision and interpretation | $74 | No |
     - | 36224 | Selective catheter placement, intracranial arterial embolization, with angiography of the intracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the extracranial carotid and cervical arterial system, when performed | $480 | No |
     - | 36226 | Selective catheter placement, vertebral arterial embolization, with angiography of the vertebral circulation and all associated radiological supervision and interpretation | $370 | No |
     - | 36238 | Selective catheter placement, each intracranial branch of the internal carotid or vertebral arteries, unilateral, with angiography of the selected vessel circulation and all associated radiological supervision and interpretation (e.g., middle cerebral artery, posterior inferior cerebellar artery) | $629 | No |

2. **CEREBRAL ANGIOGRAPHY**[11,12]
   - Selective catheter placement, each intracranial branch of the internal carotid or vertebral arteries, unilateral, with angiography of the selected vessel circulation and all associated radiological supervision and interpretation (e.g., middle cerebral artery, posterior inferior cerebellar artery) | $10.37 | No |

3. **CATHERIZATION**[13,14]
   - Selective catheter placement, arterial system, initial second order or more selective or transcatheter, or both, thoracic, or both, vascular, or both, cardiac | $79.55 | No |

4. **COMPLETION ANGIOGRAPHY**[15,16]
   - Selective catheter placement, arterial system, initial second order or more selective or transcatheter, or both, thoracic, or both, vascular, or both, cardiac | $94.99 | No |

5. **REFERENCES**
   - [14] CPT copyright 2017 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association. No fee schedules, basic units, relative values, or related listings are specifically assigned for placement of a dilation stent to open vessel stenosis. This is the opposite effect of the Pipeline™ Flex device, which excludes the aneurysm by partially closing a vessel.
   - [15] RVUs described in this chapter, Diagnostic Studies of Cervicocerebral Arteries heading, catheterization is already included in the diagnostic cerebral angiography codes. Likewise, catheterization is not coded if balloon-occlusion test is performed during the same operative procedure because catheterization in already subsumed into the codes for the angiography. See also 2011 Interventional Radiology Coding Update, SIR and ACR, p.22 FAQ-4.
   - [16] Code 61624 can be assigned multiple times, even for each completion catheterization that starts a new trauma. However, codes 61624-61635 are not displayed here because they are conventionally assigned by the referring physician; that is, the referring physician is responsible for selecting the codes.
ESSENTIAL PRESCRIBING INFORMATION (EPI) STATEMENT:
The Pipeline™ Flex embolization device should be used only by physicians trained in percutaneous, intravascular techniques and procedures at medical facilities with the appropriate fluoroscopy equipment. 

Indications for Use: The Pipeline™ Flex embolization device is indicated for the endovascular treatment of adults (22 years of age or older) with large or giant wide-necked intracranial aneurysms (IAs) in the internal carotid artery from the petrous to the superior hypophyseal segments.

CAUTION: Federal (USA) law restricts this device to sale, distribution and use by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labeling supplied with each device.

Warnings: 1) Resheathing of the Pipeline™ Flex embolization device more than 2 full cycles may cause damage to the distal or proximal ends of the braid. 2) Persons with known allergy to platinum or cobalt/chromium alloy (including the major elements platinum, cobalt, chromium, nickel, molybdenum or tungsten) may suffer an allergic reaction to the Pipeline™ Flex embolization device implant. 3) Persons with known allergy to tin, silver, stainless steel or silicone elastomer may suffer an allergic reaction to the Pipeline™ Flex embolization device delivery system. 4) Do not reprocess or resterilize. Reprocessing and resterilization increase the risk of patient infection and compromised device performance. 5) Delayed rupture may occur with large and giant aneurysms. 6) Placement of multiple Pipeline™ Flex embolization devices may increase the risk of ischemic complications.

Precautions: 1) Do not use product if the sterile package is damaged. 2) Do not use the Pipeline™ Flex embolization device in patients in whom angiography demonstrates inappropriate anatomy, such as severe pre or post-aneurysmal narrowing. 3) The Pipeline™ Flex embolization device should be used only by physicians trained in percutaneous, intravascular techniques and procedures at medical facilities with the appropriate fluoroscopic equipment. 4) Physicians should undergo appropriate training prior to using the Pipeline™ Flex embolization device in patients. 5) The Pipeline™ Flex embolization device is provided sterile for single use only. Store in a cool, dry place. 6) Carefully inspect the sterile package and device components prior to use to verify that they have not been damaged during shipping. Do not use kinked or damaged components. 7) Use the Pipeline™ Flex embolization device system prior to the “Use By” date printed on the package. 8) The appropriate anti-platelet and anti-coagulation therapy should be administered in accordance with standard medical practice. 9) A thrombosing aneurysm may aggravate pre-existing, or cause new, symptoms of mass effect and may require medical therapy. 10) Do not attempt to reposition after deployment. 11) Do not use in patients in whom the angiography demonstrates the anatomy is not appropriate for endovascular treatment, due to conditions such as severe intracranial vessel tortuosity or stenosis. 12) Use of implants with labeled diameter larger than the parent vessel diameter may result in decreased effectiveness and additional safety risk due to incomplete foreshortening resulting in an implant longer than anticipated.

Potential Complications: Potential complications, some of which could be fatal, include, but are not limited to the following: Adverse reaction to anti-platelet/anticoagulation agents or contrast media, Blindness, Coma, Device fracture, Device migration or misplacement, Dissection of the parent artery, Embolism, Groin injury, Headache, Hemorrhage, Hydrocephalus, Infection, Intracranial bleeding, Ischemia, Mass effect, Neurological deficits, Parent Artery Stenosis, Perforation, Perforator occlusion, Postprocedure bleeding, Ruptured or perforated aneurysm, Seizure, Stroke, Thromboembolism, Transient Ischemic Attack (TIA), Vasospasm, Vessel occlusion, Vessel perforation, Vision impairment. Contraindications: The use of the Pipeline™ Flex embolization device is contraindicated for patients with any of the following conditions: 1) Patients with active bacterial infection. 2) Patients in whom dual antiplatelet therapy (aspirin and clopidogrel) is contraindicated. 3) Patients who have not received dual antiplatelet agents prior to the procedure. 4) Patients in whom a pre-existing stent is in place in the parent artery at the target aneurysm location.