ONYX™ LIQUID EMBOLIC SYSTEM
CODING AND REIMBURSEMENT GUIDE
ONYX™ liquid embolic system (Onyx™ LES) is comprised of EVOH (ethylene vinyl alcohol) copolymer dissolved in DMSO (dimethyl sulfoxide), and suspended micronized tantalum powder to provide contrast for visualization under fluoroscopy.

Onyx™ LES is available in two product formulations, Onyx™ 18 (6% EVOH) and Onyx™ 34 (8% EVOH).

Onyx™ LES is used for the pre-surgical embolization of brain arteriovenous malformations (bAVMs).

For Medicare patients, procedures using ONYX™ liquid embolic system are required to be performed in the hospital inpatient setting.
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. 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 (eg, 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.

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**¹ – effective October 1, 2018

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>I60.8</td>
<td>Other nontraumatic subarachnoid hemorrhage</td>
</tr>
<tr>
<td>Q28.2</td>
<td>Arteriovenous malformation of cerebral vessels</td>
</tr>
</tbody>
</table>

**ICD-10-PCS PROCEDURE CODES**² – effective October 1, 2018

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>03LG3DZ</td>
<td>Occlusion of intracranial artery with intraluminal device, percutaneous approach</td>
</tr>
<tr>
<td>B31R1ZZZ</td>
<td>Fluoroscopy of intracranial arteries using low osmolar contrast</td>
</tr>
<tr>
<td>B31RYZZZ</td>
<td>Fluoroscopy of Intracranial Arteries using Other Contrast⁷</td>
</tr>
</tbody>
</table>
DRG ASSIGNMENT FY2019 – effective October 1, 2018

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.

<table>
<thead>
<tr>
<th>MS-DRG</th>
<th>MS-DRG TITLE</th>
<th>FY 2019 RELATIVE WEIGHT</th>
<th>FY 2019 GEOMETRIC MEAN LENGTH OF STAY</th>
<th>FY 2019 SUBJECT TO PACT</th>
<th>FY 2019 MEDICARE NATIONAL AVERAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>020</td>
<td>Intracranial Vascular Procedures W Principal Diagnosis of Hemorrhage W MCC</td>
<td>10.4253</td>
<td>13.6</td>
<td>No</td>
<td>$63,652</td>
</tr>
<tr>
<td>021</td>
<td>Intracranial Vascular Procedures W Principal Diagnosis of Hemorrhage W CC</td>
<td>7.9056</td>
<td>12.1</td>
<td>No</td>
<td>$48,268</td>
</tr>
<tr>
<td>022</td>
<td>Intracranial Vascular Procedures W Principal Diagnosis of Hemorrhage WO CC/MCC</td>
<td>5.1575</td>
<td>6.3</td>
<td>No</td>
<td>$31,489</td>
</tr>
<tr>
<td>025</td>
<td>Craniotomy and Endovascular Intracranial Procedures W MCC</td>
<td>4.2775</td>
<td>6.7</td>
<td>Yes</td>
<td>$26,116</td>
</tr>
<tr>
<td>026</td>
<td>Craniotomy and Endovascular Intracranial Procedures W CC</td>
<td>3.0157</td>
<td>4.3</td>
<td>Yes</td>
<td>$18,412</td>
</tr>
<tr>
<td>027</td>
<td>Craniotomy and Endovascular Intracranial Procedures WO CC/MCC</td>
<td>2.4057</td>
<td>2.1</td>
<td>Yes</td>
<td>$14,688</td>
</tr>
</tbody>
</table>
PHYSICIAN PROCEDURE CODING AND PAYMENT FOR ONYX™ LIQUID EMBOLIC SYSTEM

Physicians use CPT® codes for all services.

Under Medicare’s Resource-Based Relative Value Scale (RBRVS) methodology for physician payment, each CPT® code is assigned a point value, the relative value unit (RVU), which is then converted to a flat payment amount.

### CPT® CODES [12] – effective January 1, 2019

<table>
<thead>
<tr>
<th>CODE</th>
<th>CODE DESCRIPTION</th>
<th>MULTIPLE PROCEDURE DISCOUNTING</th>
<th>CY2019 MEDICARE RVUS (FACILITY SETTING)</th>
<th>CY2019 MEDICARE NATIONAL AVERAGE (FACILITY SETTING)</th>
</tr>
</thead>
<tbody>
<tr>
<td>61624</td>
<td>Transcathether permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method, central nervous system (intracranial, spinal cord)</td>
<td>Yes</td>
<td>33.71</td>
<td>$1215</td>
</tr>
<tr>
<td>75894-26</td>
<td>Transcathether therapy, embolization, any method, radiological supervision and interpretation</td>
<td>No</td>
<td>2.06</td>
<td>$74</td>
</tr>
<tr>
<td>61623</td>
<td>Endovascular temporary balloon arterial occlusion, head or neck (extracranial/ intracranial) including selective catheterization of vessel to be occluded, positioning and inflation of occlusion balloon, concomitant neurological monitoring, and radiologic supervision and interpretation of all angiography required for balloon occlusion and to exclude vascular injury post occlusion</td>
<td>Yes</td>
<td>16.61</td>
<td>$599</td>
</tr>
<tr>
<td>36224</td>
<td>Selective catheter placement, internal carotid artery, unilateral, with angiography of the ipsilateral intracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the extracranial carotid and cervicocerebral arch, when performed</td>
<td>Yes</td>
<td>10.48</td>
<td>$378</td>
</tr>
<tr>
<td>36226</td>
<td>Selective catheter placement, vertebral artery, unilateral, with angiography of the ipsilateral vertebral circulation and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed</td>
<td>Yes</td>
<td>10.33</td>
<td>$372</td>
</tr>
<tr>
<td>+36228</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 (eg, middle cerebral artery, posterior inferior cerebellar artery)</td>
<td>No</td>
<td>7.03</td>
<td>$253</td>
</tr>
<tr>
<td>36216</td>
<td>Selective catheter placement, arterial system, initial second order or more selective thoracic or brachiocephalic branch, within a vascular family</td>
<td>Yes</td>
<td>7.93</td>
<td>$286</td>
</tr>
<tr>
<td>36217</td>
<td>Selective catheter placement, arterial system, initial third order or more selective thoracic or brachiocephalic branch, within a vascular family</td>
<td>Yes</td>
<td>9.51</td>
<td>$343</td>
</tr>
<tr>
<td>75898-26</td>
<td>Angiography through existing catheter for follow-up study for transcathether therapy, embolization, or infusion other than thrombolysis</td>
<td>No</td>
<td>2.57</td>
<td>$93</td>
</tr>
</tbody>
</table>

2. Sites of attracting a brain AV malformation (AVM) here is specified as congenital.


4. In code 03L3DZ, the fourth character represents the brain part: G-Intracranial Artery. Although there are other body part values for the carotid and vertebral arteries, these are not shown because Onyx™ is used for brain AVMs which is presented by value G. (See also Coding Clinic, 1st Q 2016, p.19.)

5. Root operation L-Occlusion is defined as completely closing an orifice or the lumen of a tubular body part. Because the objective in treating an AVM is to prevent blood flow between vein and artery by completely closing the unnatural connection, this is the proper root operation (Coding Clinic, 4th Q 2014, p.37).

6. Onyx is considered a device for coding purposes because, while applied as a liquid, it solidifies after application (Coding Clinic, 4th Q 2014 p.37).

7. Intranovel technique can be used to capture those marked “Yes” and the patient must be transferred out before the geometric mean length of stay to certain post-acute care providers, including rehabilitation hospitals, long term care hospitals, skilled nursing facilities, or to home under the care of a home health agency. When these conditions are met, the DRG payment is converted to a per diem payment and is made as double the per diem rate for the first day plus the per diem rate for each remaining day up to the full DRG payment.


9. W MCC in MS-DRG titles refers to secondary diagnosis codes that are designated as major complications or comorbidities. MS-DRGs W MCC have at least one major secondary complication or comorbidity. Similarly, W CC in MS-DRG titles refers to secondary diagnosis codes designated as other (non-major) complications or comorbidities, and MS-DRGs W CC have at least one other (non-major) secondary complication or comorbidity. MS-DRGs WO CC/MCCs have no secondary diagnoses that are designated as complications or comorbidities, major or otherwise. Note that some secondary diagnoses are only designated as CCs or MCCs when the conditions were present on admission, and do not count as CCs or MCCs when the conditions are acquired in the hospital during the stay.

10. Post-Acute Care Transfer (PACT) status refers to selected DRGs in which payment to the hospital may be reduced when the patient is discharged by being transferred out. The DRGs impacted are those marked “Yes” and the patient must be transferred out before the geometric mean length of stay to certain post-acute care providers, including rehabilitation hospitals, long term care hospitals, skilled nursing facilities, or to home under the care of a home health agency. When these conditions are met, the DRG payment is converted to a per diem rate. See also 2011 Interventional Radiology Coding Update, SIR and ACR, p.22 FAQ-4 and NCCI Edits policy and procedure and add-on code.


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13. Modifier -26 is appended to certain imaging codes to show that the physician is reporting only the professional interpretation, because the hospital is providing the imaging equipment and technician.


15. For codes marked “Yes”, multiple procedure discounting indicates that when a procedure code is reported on the same day as another higher-weighted procedure code, the highest-weighted code is paid at 100% of the fee schedule amount and additional codes are paid at 50% of the fee schedule amount. Procedure codes marked “No” are always paid at 100% of the fee schedule amount regardless of whether they are submitted with other procedure codes. January 2019 release of the PFS Relative Value File RVU19A at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files.html.

16. The total RVU as shown here is the sum of three components: physician work RVU, practice expense RVU, and malpractice RVU. RVUs and the Medicare National Average are shown for the facility setting only because the Onyx™ embolization procedure is always performed in the hospital, rather than the non-facility (physician office) setting.

17. Medicare national average payment is determined by multiplying the sum of the three RVUs by the conversion factor. Effective January 1, 2019, the conversion factor for CY2018 is $36,0391 per CY 2019 Final Rule; 83 Fed. Reg. 59356-60503. https://www.gpo.gov/fdsys/pkg/FR-2018-11-23/pdf/2018-24170.pdf. Published November 23, 2018. See also the January 2019 release of the PFS Relative Value File RVU19A at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files.html. Final payment to the physician is adjusted by the Geographic Practice Cost Index (GPCI). Also note that any applicable coinsurance, deductible, and other amounts that are patient obligations are included in the national average payment amount shown.

18. Component coding conventions apply to code 61624, so radiological supervision and interpretation is coded separately. Code 75894 represents the radiologic service linked to code 61624. The payment will also be adjusted by the Wage Index for specific geographic location. Therefore, payment for a specific hospital will vary from the stated Medicare national average payment levels shown. Also note that any applicable coinsurance, deductible, and other amounts that are patient obligations are included in the national average payment amount shown.

19. A balloon occlusion test may be performed immediately prior to Onyx™ embolization for AVM, to assess the neurological risks of permanently occluding the vessel. When per-formed, this may be coded and reported separately.

20. Codes 61624 and 75894 for Onyx™ embolization include intraprocedural road-mapping and fluoroscopic guidance necessary to perform the intervention. However, cerebral angiography may be coded separately with 61624 when it is truly diagnostic. According to CPT® manual instructions (Radiology section, Vascular Procedures heading), a truly diagnostic study means that no prior angiography is available and the decision to intervene is based on the current angiography or, if angiography was previously performed, the patient’s condition has changed since the prior angiography, there is inadequate visualization of the anatomy or pathology on prior angiography, or there is a clinical change during the procedure requiring new evaluation. See also CPT® manual instructions (Surgery section, Cardiovascular System chapter, Diagnostic Studies of Cervicocerebral Arteries heading) and NCCI Policy Manual, 01/01/2019, Chapter V, D13.

21. A 4-view cervical and cerebral angiography, from catheter placement in the internal carotid arteries and vertebral arteries bilaterally, is typically coded 36224-50 and 36226-50. Add-on code +36228 would also be assigned if additional angiography was performed from catheter placement in, for example, the superior hypophyseal artery.

22. Catheter placement may be coded separately with 61624. Code 36216 would typically represent catheterization of the left internal carotid artery. Code 36217 would typically represent catheterization of the right internal carotid artery or higher level, eg, the middle cerebral artery on either side.

23. If diagnostic cerebral angiography is also performed during the same operative encounter, catheterization is not coded at all. According to CPT Section, Cardiovascular System chapter, Diagnostic Studies of Cervicocerebral Arteries heading, catheterization is already included in the diagnostic cerebral angiography codes. b manual instructions (Surgery Likewise, catheterization is not coded if a balloon occlusion test is performed during the same operative encounter, because catheterization is already included in code 61624. Catheterization for the intervention 61624 would be subsumed into the codes for the angiography or follow-up angiogram performed during the embolization. See also 2011 Interventional Radiology Coding Update, SIR and ACR, p.22 FAQ-4 and NCCI Policy Manual, 01/01/2019, Chapter V, D13.

24. Code 75898 can be assigned multiple times, once for each completion or follow-up angiogram performed during the embolization. However, physicians are advised to assign 75898 judiciously and to maintain clear documentation on the medical necessity for each angiogram.
Indications, Contraindications, Warnings and instructions for use can be found in the product labeling supplied with each device.
CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

**ONYX™ LIQUID EMBOLIC SYSTEM (AVM): ESSENTIAL PRESCRIBING INFORMATION**
This product is for the exclusive use by medical specialists experienced in angiographic and percutaneous neurointerventional procedures.

**INDICATIONS FOR USE:** Presurgical embolization of brain arteriovenous malformations (bAVMs).

**CONTRAINDICATIONS:** The use of the Onyx™ LES is contraindicated when any of the following conditions exist:
- When optimal catheter placement is not possible.
- When provocative testing indicates intolerance to the occlusion procedure.
- When vasospasm stops blood flow.

**PRECAUTIONS:**
1. The safety and effectiveness has not been studied in the following patient populations: pregnant and nursing women, individuals less than 18 years old, individuals with aneurysms not associated with a bAVM nidus, or distal feeders to a bAVM nidus or dural AV fistulas. Some data indicate that dimethyl sulfoxide potentiates other concomitantly administered medications.
2. A garlic-like taste may be noted by the patient with use of the Onyx™ LES due to the DMSO component. This taste may last several hours.
3. An odor on the breath and skin may be present.
4. Inspect product packaging prior to use. Do not use if sterile barrier is open or damaged.
5. Use prior to expiration date.
6. Verify that the catheters and accessories (see directions for use) used in direct contact with the Onyx™ LES polymer are clean and compatible with the material and do not trigger polymerization or degrade with contact. Use only ev3 approved, Onyx™ LES/DMSO compatible micro catheters indicated for use in the neurovasculature and ev3 syringes. Other micro catheters or syringes may not be compatible with DMSO and their use can result in thromboembolic events due to catheter degradation. Refer to the Warnings and Directions for Use sections.
7. Wait a few seconds following completion of the Onyx™ LES injection before attempting catheter retrieval. Failure to wait a few seconds to retrieve the micro catheter after the Onyx™ LES injection may result in fragmentation of the Onyx™ LES into non-target vessels.

**Difficult catheter removal or catheter entrapment may be caused by any of the following:**
- Angioarchitecture: very distal bAVM fed by afferent, lengthened, small, or tortuous pedicles.
- Vasospasm, Reflux, Injection time. To reduce the risk of catheter entrapment, carefully select catheter placement and manage reflux to minimize the factors listed above.
- Should catheter removal become difficult, the following will assist in catheter retrieval: Carefully pull the catheter to assess any resistance to removal. If resistance is felt, remove any “slack” in the catheter. Gently apply traction to the catheter (approximately 3-4 cm of stretch to the catheter). Hold this traction for a few seconds and release. Assess traction on vasculature to minimize risk of hemorrhage. This process can be repeated intermittently until catheter is retrieved.

**Alternate Technique for Difficult to Remove Catheters:** Remove all slack from the catheter by putting a few centimeters of traction on the catheter to create a slight tension in the catheter system. Firmly hold the catheter and then pull it using a quick wrist snap motion (from left to right) 10 – 15 centimeters to remove the catheter from the Onyx™ LES cast (Note: Do not apply more than 20 cm of traction to catheter, to minimize risk of catheter separation).

For entrapped catheters: Under some difficult clinical situations, rather than risk rupturing the malformation and consequent hemorrhagic complications by applying too much traction on an entrapped catheter, it may be safer to leave the micro catheter in the vascular system. This is accomplished by stretching the catheter and cutting the shaft near the entry point of vascular access allowing the catheter to remain in the artery. If the catheter breaks during removal, distal migration or coil of the catheter may occur. Same day surgical resection should be considered to minimize the risk of thrombosis.

**POTENTIAL COMPLICATIONS:** The following adverse events occurred using Onyx during a prospective, randomized, multi-center clinical trial for the presurgical treatment of bAVMs: Death, Headache +/- nausea and vomiting, Patient discomfort, Laboratory/Imaging abnormalities (Endocrine/Metabolic, Hematologic, Asymptomatic MRI/CT Findings, Respiratory/Pulmonary, General, Gastrointestinal (GI)), Worsening Neurologic Status (Persistent, Resolved), Hyperglycemia, Infection, Bleeding and/or Low Hct requiring transfusion (Surgical Bleeding, Decreased Hct Requiring Transfusion), Intracranial Hemorrhage, Medication reaction, Failed access, Access site bleeding, Fever, Delivery Catheter removal difficulty, Poor penetration/visualization, Hypopotension, Stroke, Cardiac arrhythmia, Hydrocephalus, SIADH (Syndrome of inappropriate antidiuretic hormone secretion, dilutional hyponatremia), Vessel Dissection, Hypertension, Limb ischemia, Respiratory failure, Seizures, UTI (Urinary tract infection), Vasospasm, Vaso-vagal episode, catheter shaft rupture, delivery catheter rupture, fragmentation of the Onyx™ LES, hypoxia, laryngospasm, peptic ulcer disease, psychotic episode, pulmonary edema, skin abrasion, subintimal injection, tachypnea, and tongue swelling.