Endovascular Stent Grafts for Abdominal Aortic Aneurysms

Policy # 00035
Original Effective Date: 01/27/2003
Current Effective Date: 06/19/2019

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Endovascular Stent Grafts for Disorders of the Thoracic Aorta is addressed separately in medical policy 00181.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider endoprostheses as a treatment of abdominal aortic aneurysms (AAAs) to be eligible for coverage.**

Patient Selection Criteria
Coverage eligibility for the use of endoprostheses will be considered when all of the following criteria are met:

- The device is U.S. Food and Drug Administration (FDA) approved for the treatment of AAAs and is used according to the U.S. FDA labeling
- As a treatment of AAAs in any of the following clinical situations:
  - An aneurysmal diameter greater than 5cm; or
  - An aneurysmal diameter of 4-5cm that has increased in size by 0.5cm in the last 6 months; or
  - An aneurysmal diameter that measures twice the size of the normal infrarenal aorta; or
- A ruptured AAA (see Policy Guidelines section).
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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

The use of endoprostheses approved by the U.S. FDA as a treatment of AAAs are considered to be investigational*, including but not limited to the following clinical situations:

- Treatment of smaller aneurysms that do not meet the current recommended threshold for surgery;
- Treatment of aneurysms that do meet the recommended threshold for surgery in patients who are ineligible for open repair due to physical limitations or other factors.

The use of endoprostheses when patient selection criteria are not met is considered investigational.*

Policy Guidelines

For treatment of ruptured abdominal aortic aneurysms with endoprostheses, several factors must be considered including the following:

- The patient must be sufficiently stable to undergo detailed computed tomography examination for anatomic measurements,
- The aneurysm should be anatomically appropriate for endovascular repair, and
- Specialized personnel should be available.

To monitor for leaking of the graft after implantation, patients will typically undergo routine imaging with computed tomography or ultrasonography every 6 to 12 months, or more frequently if perivascular leaks or aneurysm enlargement are detected.

Background/Overview

Conventional management of a clinically significant abdominal aortic aneurysm (AAA) consists of surgical excision with the placement of a sutured woven graft. Surgical excision is associated with a perioperative mortality rate between 1% and 5%. Perioperative morbidity and mortality are highest in older female patients with cardiac, pulmonary, or kidney disease; the most common cause of death is multisystem organ failure.
Due to the high mortality rate, endovascular prostheses have been developed as a less risky and minimally invasive, catheter-based alternative to open surgical excision of AAAs. These devices are deployed across the aneurysm such that the aneurysm is effectively “excluded” from the circulation, with subsequent restoration of normal blood flow.

The main potential advantage of endovascular grafts for an AAA is that they offer a less invasive and less risky approach to the repair of abdominal aneurysms. While the use of an endovascular approach has the potential to reduce the relatively high perioperative morbidity and mortality associated with open AAA repair, use of endovascular grafts also has potential disadvantages. In particular, there are concerns about the durability of the anchoring system, aneurysm expansion, and other late complications related to the prosthetic graft. Aneurysm expansion may result from perivascular leaks, also known as endoleaks, which are a unique complication of endoprostheses. Perivascular leaks may result from an incompetent seal at one of the graft attachment sites, blood flow in aneurysm tributaries (these tributaries are ligated during open surgery), or perforation of graft fabric.

Several types of grafts are currently in use: straight grafts, in which both ends are anchored to the infrarenal aorta, and bifurcated grafts, in which the proximal end is anchored to the infrarenal aorta, and the distal ends are anchored to the iliac arteries. Fenestrated grafts have also been investigated. These grafts are designed with openings in the wall that can be placed across the renal or celiac arteries while still protecting vessel patency through these critical arteries. Also, extensions can be placed from inside the main endograft body into the visceral arteries to create a hemostatic seal.

**FDA or Other Governmental Regulatory Approval**

**U.S. Food and Drug Administration (FDA)**

A large number of endovascular grafts have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (PMA) process for treatment of AAAs (see Table 1). The original PMA dates are shown. Most stents have undergone device modification, name changes, and have approved supplements to the original PMA. FDA product code MIH.
Table 1. Abdominal Aortic Stent Grafts Approved by FDA

<table>
<thead>
<tr>
<th>Stent Name</th>
<th>PMA Applicant</th>
<th>Approved</th>
<th>PMA No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>AneuRx® ‡ Prosthesis System (AneuRx AAAdvantage Stent Graft)</td>
<td>Medtronic Vascular</td>
<td>1999</td>
<td>P990020</td>
</tr>
<tr>
<td>Ancure® ‡ Aortoiliac System</td>
<td>Guidant Endovascular Technologies</td>
<td>2002</td>
<td>P990017</td>
</tr>
<tr>
<td>Gore® ‡ Excluder® ‡</td>
<td>W.L. Gore &amp; Associates</td>
<td>2002</td>
<td>P020004</td>
</tr>
<tr>
<td>Zenith® ‡ AAA Endovascular Graft</td>
<td>Cook</td>
<td>2003</td>
<td>P020018</td>
</tr>
<tr>
<td>Endologix Powerlink® ‡ (Afx Endovascular AAA system)</td>
<td>Endologix</td>
<td>2004</td>
<td>P040002</td>
</tr>
<tr>
<td>Talent® ‡ Abdominal Stent Graft System</td>
<td>Medtronic</td>
<td>2008</td>
<td>P070027</td>
</tr>
<tr>
<td>Endurat® ‡ II AAA Stent Graft System</td>
<td>Medtronic</td>
<td>2010</td>
<td>P100021</td>
</tr>
<tr>
<td>Valiant Thoracic Stent Graft System</td>
<td>Medtronic</td>
<td>2011</td>
<td>P100040</td>
</tr>
<tr>
<td>Relay Thoracic Stent-Graft with Plus Delivery System</td>
<td>Bolton Medical</td>
<td>2012</td>
<td>P110038</td>
</tr>
<tr>
<td>Ovation™ ‡ Abdominal Stent Graft System</td>
<td>TriVascular</td>
<td>2012</td>
<td>P120006</td>
</tr>
<tr>
<td>Aorfix™ ‡ AAA Flexible Stent Graft System</td>
<td>Lombard Medical</td>
<td>2013</td>
<td>P110032</td>
</tr>
</tbody>
</table>

FDA: Food and Drug Administration; PMA: premarket approval.

Rationale/Source

Endovascular stent grafts can be used as minimally invasive alternatives to open surgical repair for treatment of abdominal aortic aneurysms (AAAs). Open surgical repair of AAAs has high morbidity and mortality, and endovascular grafts have the potential to reduce the operative risk associated with AAA repair.

For individuals who have AAAs eligible for open repair who receive endovascular stent grafts, the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. Evidence from a patient-level meta-analysis of 4 RCTs comparing endovascular aneurysm repair (EVAR) with open repair for elective treatment of AAAs has indicated that neither approach is clearly superior to the other. While EVAR is associated with an early reduction in mortality, outcomes at 5 years or longer have shown greater reintervention rates and endovascular mortality.
and comparable overall survival rates for EVAR and open repair. Thus, the early advantage of EVAR is offset by a higher rate of late complications over the long term. Based on these data, EVAR may be considered as an alternative to open surgery in patients who are candidates for both procedures. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have ruptured AAAs who receive endovascular stent grafts, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. For patients with ruptured AAAs, evidence from 4 RCTs and a patient-level meta-analysis has indicated that short- and intermediate-term survival following EVAR is comparable with open repair. Evidence from RCTs and nonrandomized matched comparisons has shown that EVAR is associated with lower perioperative morbidity. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have AAAs ineligible for open repair who receive endovascular stent grafts, the evidence includes RCTs. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. At least 2 RCTs have compared EVAR with no surgical intervention for patients ineligible for open repair, either because of aneurysm size or prohibitive surgical risk. These trials did not report superior outcomes with EVAR and thus do not support the use of EVAR in this population. The evidence is sufficient to determine that the technology is unlikely to improve the net health outcome.

**Supplemental Information**

**Practice Guidelines and Position Statements**

**American College of Cardiology Foundation and American Heart Association**

Updated guidelines on the management of abdominal aortic aneurysms (AAAs) were released by the American College of Cardiology Foundation and the American Heart Association in 2011 as a focused update to the 2005 guidelines on the management of patients with peripheral artery disease. These guidelines made the following recommendations (see Table 3).
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Table 3. Guidelines on Management of Patients With Peripheral Artery Disease

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open or endovascular repair of infrarenal AAAs and/or common iliac aneurysms is indicated in patients who are good surgical candidates</td>
<td>I</td>
<td>A</td>
</tr>
<tr>
<td>Periodic long-term surveillance imaging should be performed to monitor for endoleak, confirm graft position, document shrinkage or stability of the excluded aneurysm sac, and determine the need for further intervention in patients who have undergone endovascular repair of infrarenal aortic and/or iliac aneurysms</td>
<td>I</td>
<td>A</td>
</tr>
<tr>
<td>Open aneurysm repair is reasonable to perform in patients who are good surgical candidates but who cannot comply with the periodic long-term surveillance required after endovascular repair</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>Endovascular repair of infrarenal aortic aneurysms in patients who are at high surgical or anesthetic risk as determined by the presence of coexisting severe cardiac, pulmonary, and/or renal disease is of uncertain effectiveness</td>
<td>IIb</td>
<td>C</td>
</tr>
</tbody>
</table>

AAA: abdominal aortic aneurysm; COR: class of recommendation; LOE: level of evidence. Professional guidelines from the American College of Cardiology and American Heart Association (2006), based on both randomized and nonrandomized trials, have suggested that endovascular repair of infrarenal aortic and/or common iliac aneurysms is reasonable in patients at high risk of complication from open surgeries.

Society of Interventional Radiology

Guidelines on the use of endovascular aneurysm repair (EVAR) were developed by the Society of Interventional Radiology in 2010 and endorsed by the Cardiovascular and Interventional Radiological Society of Europe and the Canadian Interventional Radiology Association. These guidelines indicated that:

"Indications for EVAR are currently the same as open repair….”

"Patient preference for EVAR versus open repair should be considered when appropriate….”

"Endovascular abdominal aortic aneurysm repair should be considered as having an intermediate to high cardiac risk that ranges from 3% to 7%. “
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There has been increasing use of EVAR for ruptured aneurysms. “Achieving optimal EVAR results for ruptured AAA requires establishment of a treatment protocol involving the emergency department, the endovascular team, anesthesiology, and the operating room personnel.”

“Lifelong imaging surveillance of patients after EVAR is critical for (i) the detection and, if possible, the characterization of endoleaks; (ii) evidence of expansion or shrinkage of the residual AAA sac through measurement of aneurysm size, volume calculation, and identification of substantial changes in aneurysm dimensions; (iii) detection of mechanical changes in the stent-graft, such as migration, kinking, or fracture; and (iv) evaluation of the long-term performance of the endoprosthesis.”

Society for Vascular Surgery
The Society for Vascular Surgery published guidelines for the treatment of AAAs in 2018. As in previous publications, these guidelines indicated that open surgery and EVAR are options for patients with aneurysms that meet the current treatment threshold. These guidelines also made the following recommendations (see Table 4).

Table 4. Guidelines on Management of Patients With Aneurysms

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>QOE</th>
<th>LOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>EVAR is progressively replacing open surgery as the treatment of choice, and accounts for more than half of all elective AAA repairs in the United States</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emergent EVAR should be considered for treatment of a ruptured AAA, if anatomically feasible</td>
<td>Moderate</td>
<td>Strong</td>
</tr>
<tr>
<td>EVAR may be considered for high-risk patients unfit for surgical repair</td>
<td>Low</td>
<td>Weak</td>
</tr>
<tr>
<td>For patients with ruptured aneurysm, immediate repair is recommended</td>
<td>High</td>
<td>Strong</td>
</tr>
</tbody>
</table>


U.S. Preventive Services Task Force Recommendations
Not applicable.
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Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are in Table 5.

Table 5. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01878240</td>
<td>Prevention of Type II Endoleaks During Endovascular Treatment of Abdominal Aortic Aneurysm: Endovascular Treatment Versus Combination With Coil Embolisation of the Aneurysmal Sac</td>
<td>100</td>
<td>May 2019</td>
</tr>
<tr>
<td>NCT00583050</td>
<td>Endovascular Exclusion of Thoracoabdominal Aortic Aneurysms or Abdominal Aneurysms Utilizing Fenestrated/Branched Stent-Grafts</td>
<td>1440</td>
<td>Dec 2020</td>
</tr>
<tr>
<td>NCT01937949†</td>
<td>Clinical Outcomes and Quality of Life Measures in Patients Treated for Complex Abdominal Aortic Aneurysms With Fenestrated Stent Grafts</td>
<td>200</td>
<td>Dec 2020</td>
</tr>
<tr>
<td>NCT03446287</td>
<td>Clinical Outcomes and Quality of Life Measures in Patients Treated With Open Surgical Repair for Complex Aortic Aneurysms</td>
<td>150</td>
<td>Dec 2020</td>
</tr>
<tr>
<td>NCT01726257†</td>
<td>Prospective, Multicenter, Single Arm Safety and Effectiveness Study of Endovascular Abdominal Aortic Aneurysm Repair Using the Nellix®‡ System: A Pivotal and Continued Access Study</td>
<td>429</td>
<td>Jun 2021</td>
</tr>
<tr>
<td>NCT02485496†</td>
<td>SECURE - A post-market Registry in Patients With infraEnal aortic Aneurysm Undergoing endovascular Stenting With the New E-tegra Stent Graft System</td>
<td>100</td>
<td>Oct 2021</td>
</tr>
</tbody>
</table>
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## Clinical Trials

<table>
<thead>
<tr>
<th>Trial ID</th>
<th>Title</th>
<th>Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT02996396*</td>
<td>Multicenter, Observational, Registry to Assess Outcomes of Patients Treated With the CE Nellix™‡ System for Endovascular Abdominal Aortic Aneurysm Repair</td>
<td>300</td>
<td>Oct 2023</td>
</tr>
<tr>
<td>NCT03298477*</td>
<td>Prospective, Multicenter, Single Arm Safety and Effectiveness Confirmatory Study of Endovascular Abdominal Aortic Aneurysm Repair Using the Nellix System IDE Study (EVAS 2 Confirmatory IDE Study)</td>
<td>90</td>
<td>May 2024</td>
</tr>
<tr>
<td>NCT02489539*</td>
<td>Assessment of the Gore®‡ Excluder®‡ Conformable AAA Endoprosthesis in the Treatment of Abdominal Aortic Aneurysms</td>
<td>190</td>
<td>Dec 2024</td>
</tr>
<tr>
<td>NCT03180996*</td>
<td>A Prospective, Global, Multicentre, Real World Outcome Study of Fenestrated Endovascular Aneurysm Repair Using the Fenestrated Anaconda™‡ Device</td>
<td>160</td>
<td>Sep 2029</td>
</tr>
<tr>
<td>NCT00583414</td>
<td>Endovascular Exclusion of Abdominal Aortic Aneurysms in High Risk Patients</td>
<td>400</td>
<td>Oct 2017 (completed)</td>
</tr>
</tbody>
</table>

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**References**


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*NCT:* national clinical trial.  
*a* Denotes an industry-sponsored or cosponsored trial.

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Policy History
Original Effective Date: 01/27/2003
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11/21/2002 Medical Policy Committee review
01/27/2003 Managed Care Advisory Council approval
01/26/2004 Managed Care Advisory Council approval
01/04/2005 Medical Director review
01/18/2005 Medical Policy Committee review. Format revision. Coverage eligibility unchanged
01/31/2005 Managed Care Advisory Council approval
05/17/2005 Medical Policy Committee review. Format revision. Policy statement changed from endoprostheses (i.e., endovascular grafts) as a treatment of abdominal aortic aneurysms (infrarenal abdominal or aortoiliac aneurysms) to: the use of FDA-approved endoprostheses as a treatment of abdominal aortic aneurysms. Patient selection criteria expanded to include; “The use of FDA-approved endoprostheses as a treatment of abdominal aortic aneurysms may be considered medically necessary as a treatment of abdominal aortic aneurysms in any of the following clinical situations, consistent with the FDA-labeled indications for the AneurRx device.” Investigational statement added to address non FDA-Approved devices and situations when patient selection criteria are not met.
05/23/2005 Managed Care Advisory Council approval
07/07/2006 Format revision; including, addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
08/02/2006 Medical Director Review
06/13/2007 Medical Director review
08/06/2009 Medical Policy Committee approval
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08/26/2009 Medical Policy Implementation Committee approval. No change to coverage eligibility.
07/01/2010 Medical Policy Committee approval
07/21/2010 Medical Policy Implementation Committee approval. Changed coverage statement from investigational to eligible for coverage with criteria for ruptured abdominal aortic aneurysms.
07/07/2011 Medical Policy Committee review
07/20/2011 Medical Policy Implementation Committee approval. For clarification, added that the use of endoprostheses approved by the U.S. FDA as a treatment of abdominal aortic aneurysms is considered investigational for certain clinical situations.
06/28/2012 Medical Policy Committee review
07/27/2012 Medical Policy Implementation Committee approval. No change to coverage.
03/04/2013 Coding revised
06/27/2013 Medical Policy Committee review
07/17/2013 Medical Policy Implementation Committee approval. No change to coverage.
07/10/2014 Medical Policy Committee review
07/16/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/04/2015 Medical Policy Committee review
06/17/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
06/02/2016 Medical Policy Committee review
06/20/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
06/01/2017 Medical Policy Committee review
06/21/2017 Medical Policy Implementation Committee approval. Added “stent” to the title. Coverage eligibility unchanged.
01/01/2018 Coding update
06/07/2018 Medical Policy Committee review
06/20/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
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06/06/2019 Medical Policy Committee review
06/19/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 06/2020

Coding
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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>0254T, 34701, 34702, 34703, 34704, 34705, 34706, 34707, 34708, 34709, 34710, 34711, 34712, 34713, 34714, 34715, 34716, 34808, 34812, 34813, 34820, 34833, 34834, 34841, 34842, 34843, 34844, 34845, 34846, 34847, 34848</td>
</tr>
<tr>
<td>HCPCS</td>
<td>No codes</td>
</tr>
<tr>
<td>ICD-10 Diagnosis</td>
<td>171.02  171.3   171.4   171.8</td>
</tr>
</tbody>
</table>

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:
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A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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