I. Policy: Intracranial Percutaneous Transluminal Angioplasty

II. Purpose/Objective:
To provide a policy of coverage regarding Intracranial Percutaneous Transluminal Angioplasty

III. Responsibility:
A. Medical Directors
B. Medical Management

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) The service or benefit will assist the Member to achieve or maintain maximum functional
capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION:
Intracranial Percutaneous Transluminal Angioplasty has been proposed to improve cerebral artery lumen diameter in patients with intracranial atherosclerotic disease and cerebral vasospasm after aneurysmal subarachnoid hemorrhage. The device consists of a self-expanding, nitinol stent sheathed in a delivery system that enables it to reach and to open narrowed arteries in the brain.

The use of an intracranial stent in conjunction with endovascular coil embolization of a wide-neck intracranial aneurysm (See MP 211) is considered medically necessary.

LIMITATIONS:
For Medicare and Medicaid Business Segment, intracranial percutaneous transluminal angioplasty with stenting may be considered medically necessary for the treatment of cerebral artery stenosis ≥50% in patients with intracranial atherosclerotic disease when furnished in accordance with the FDA-approved protocols governing Category-B Investigational Device Exemption (IDE) clinical trials.

EXCLUSIONS:
Although the device is FDA approved, there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of Intracranial Percutaneous Transluminal Angioplasty on health outcomes when compared to established treatments or technologies. For all lines of business except Medicare and Medicaid products, the use of Intracranial Percutaneous Transluminal Angioplasty with or without stenting, for the treatment of intracranial atherosclerotic disease and cerebral vasospasm after aneurysmal subarachnoid hemorrhage is considered experimental, investigational or unproven. The benefit for Medicare and Medicaid products will be in accordance to CMS mandated coverage as outlined in the current version of National Coverage Determination.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Intracranial Percutaneous Transluminal Angioplasty

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

61630 Balloon angioplasty, intracranial (eg. Atherosclerotic stenosis), percutaneous
61635 Transcatheter placement of intravascular stent(s), intracranial (eg. Atherosclerotic stenosis), including balloon angioplasty, if preformed.
61640 Balloon dilatation of intracranial vasospasm, percutaneous, intial vessel
61641 Balloon dilation of intracranial vasospasm, percutaneous; each additional vessel in same vascular family (List Separately in addition to code for primary procedure)
61642 Balloon dilation of intracranial vasospasm, percutaneous; each additional vessel in different vascular family (List Separately in addition to code for primary procedure)


LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD’s and NCD’s will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:


CMS National Coverage Determinations Manual. 20.7 - Percutaneous Transluminal Angioplasty. Last Revised January 19, 2018


This policy will be revised as necessary and reviewed no less than annually.

Devised: 06/2006

Revised: 1/08 (added coil embolization limitation), 1/20 (revised layout, no clinical changes)

Reviewed: 1/09, 1/10, 2/11, 2/12, 2/13, 2/14, 2/15, 2/16, 1/17,1/18, 1/19