Clinical Policy: Aspirin/Extended-release Dipyridamole (Aggrenox)
Reference Number: HIM.PA.55
Effective Date: 12/14
Last Review Date: 08/17 Revision Log
Line of Business: Health Insurance Marketplace

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Aggrenox/extended-release dipyridamole (Aggrenox®) is a combination antiplatelet agent.

FDA approved indication
Aggrenox is indicated to reduce the risk of stroke in patients who have had transient ischemia of the brain or completed ischemic stroke due to thrombosis.

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

I. Initial Approval Criteria

A. Secondary Prevention of Stroke (must meet all)**:**

1. Age ≥ 18 years;
2. Medical history includes ischemic stroke or transient ischemic attack (TIA);
3. Failure of aspirin used as a single agent (e.g., stroke or TIA while on aspirin therapy);
4. Member is not a candidate for clopidogrel (Plavix) therapy due to contraindications or clinically significant adverse effects/drug interactions;
5. If request is for the branded version, member has contraindications or clinically significant adverse effects to excipients in the generic version;
6. Dose does not exceed 400 mg/day extended-release dipyridamole and 50 mg/day aspirin (2 tablets per day).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Secondary Prevention of Stroke (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. If request is for a dose increase, new dose does not exceed 400 mg/day extended-release dipyridamole and 50 mg/day aspirin (2 tablets/day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to HIM.PA.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – HIM.PHAR.21 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation Key
FDA: Food and Drug Administration
TIA: transient ischemic attack

V. References

1. Aggrenox Prescribing Information. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc.; November 2015. Available at: http://docs.boehringer-ingelheim.com/Prescribing%20Information/PIs/Aggrenox%20Caps/Aggrenox.pdf. Accessed on January 18, 2017.
2. Goldstein LB, Bushnell CD, Adams RJ, et al. Guidelines for the Primary Prevention of Stroke. Stroke 2011; 42: 517-584. http://stroke.ahajournals.org/content/42/2/517
3. Aggrenox Drug Monograph. Clinical Pharmacology. Accessed January 18, 2017. http://www.clinicalpharmacology-ip.com
4. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 18, 2017.
5. Kernan WN, Ovbiagele B, Black HR, et al. Guidelines for prevention of stroke in patients with stroke and transient ischemic attack: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2014; 45(7): 2160-2236.
6. Lansberg MG, O'Donnell MJ, Khatri P et al. Antithrombotic and thrombolytic therapy for ischemic stroke: antithrombotic therapy and prevention of thrombosis, 9th ed.: American College of Chest Physicians evidence-based clinical practice guidelines. Chest. 2012; 141(2 Suppl): e601S-636S.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Changed guideline to new format. Streamlined approval criteria. Removed prior authorization requirement off of generic version of Aggrenox. Added criteria E for approval of brand product.	08/16	
Removed requirement for diagnosis of stroke to have been made by a neurology specialist or in consult with a neurologist or vascular specialist as other specialties can diagnose stroke (plus, documentation to support diagnosis is now required per new template)	04/17	08/17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Modified stroke diagnosis criteria to exclude the word "recent" as 1) there is no defined time frame for recent and 2) antiplatelet therapy is indicated for secondary prevention in all stroke patients regardless of when the stroke occurred Added age limit since aspirin is unsafe to use in pediatric patients due to risk of Reye's syndrome		

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to

recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.