# Clinical Policy: Aspirin/dipyridamole (Aggrenox)

Reference Number: PA.CP.PMN.20
Effective Date: 01/18
Last Review Date: 07/18

Coding Implications
Revision Log

**Description**
Aspirin/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 **

It is the policy of Pennsylvania Health and Wellness ® that Aggrenox is **medically necessary** when the following criteria are met:

**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) or other medical necessity justification provided by the prescriber;
4. Member is not a candidate for clopidogrel (Plavix) therapy due to contraindications or clinically significant adverse effects/drug interactions;
5. Request does not exceed 50 mg aspirin/400 mg extended-release dipyridamole per day (2 tablets per day).

**Approval duration: 12 months**

**B.** Other diagnoses/indications – Refer to PA.CP.PMN.53 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 Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. If request is for a dose increase, new dose does not exceed 50 mg aspirin/400 mg extended-release dipyridamole per day (2 tablets per day).

**Approval duration: 12 months**

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or the Continuity of Care policy (PA.LTSS.PHAR.01) applies and documentation supports positive response to therapy; or
2. Refer to PA.CP.PMN.53 if requested indication is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

**Approval duration: 12 months**

## 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 – PA.CP.PMN.53 or evidence of coverage documents

## IV. Appendices/General Information

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

## V. Dosage and Administration

- The recommended dose of Aggrenox is one capsule swallowed whole (no chewing) twice daily (morning and evening) with or without food.
- In case of intolerable headaches during initial treatment, switch to one capsule at bedtime and low-dose aspirin in the morning; resume twice daily dosing within one week.
- Aggrenox is not interchangeable with individual components of aspirin and dipyridamole tablets.

## VI. Product Availability

Capsule: 25 mg aspirin/200 mg extended-release dipyridamole

## VII. References

1. Aggrenox Prescribing Information. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc.; November 2015. Available at: https://www.aggrenox.com. Accessed October 30, 2017.
2. 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.
3. 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 | Approval Date |
|---|---|---|
| References reviewed and updated. | 02/18 | |