

## Clinical Policy: Nitroglycerin (GoNitro)

Reference Number: CP.CPA.257

Effective Date: 02.01.17

Last Review Date: 11.19

Line of Business: Commercial

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

Nitroglycerin (GoNitro™) is an organic nitrate that is a vasodilator which has effects on both arteries and veins.

### FDA Approved Indication(s)

GoNitro is indicated for acute relief of an attack or prophylaxis of angina pectoris due to coronary artery disease.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation® that GoNitro is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Angina (must meet all):

1. Diagnosis of coronary artery disease requiring angina prophylaxis;
2. Documentation supports inability to use generic sublingual nitroglycerin tablets (generic Nitrostat®).

**Approval duration: Length of Benefit**

##### B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

#### II. Continued Therapy

##### A. Angina (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria.

**Approval duration: Length of Benefit**

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

**Approval duration: Duration of request or 12 months (whichever is less); or**

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

**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 – CP.CPA.09 for commercial or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
nitroglycerin sublingual tablets (Nitrostat)	0.3 to 0.6 mg every 5 minutes for a maximum of 3 tablets in 15 minutes; may also use prophylactically 5 to 10 minutes prior to activities which may provoke an attack	1.8 mg within 15 minutes

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s):
  - Use of phosphodiesterase type 5 inhibitors, such as avanafil, sildenafil, tadalafil, or vardenafil, or soluble guanylate cyclase stimulators;
  - Severe anemia;
  - Increased intracranial pressure;
  - Hypersensitivity to GoNitro or to other nitrates or nitrates or any excipient;
  - Circulatory failure and shock.
- Boxed warning(s): none reported

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
Angina	At the onset of an attack, administer one or two packets (400 mcg each) under the tongue. One additional packet may be administered every 5 minutes as needed. No more than three total packets (1200 mcg) are recommended within a 15 minute period.	1,200 mcg within 15 minutes

Indication	Dosing Regimen	Maximum Dose
	<p>If chest pain persists after three packets, seek prompt medical attention.</p> <p>May be used prophylactically 5 to 10 minutes prior to engaging in activities that might precipitate an acute attack.</p>	

**VI. Product Availability**

Sublingual powder: 400 mcg/packet

**VII. References**

1. GoNitro Prescribing Information. Jacksonville, FL: Espero Pharmaceuticals, Inc.; June 2016. Available at: [www.gonitropowder.com](http://www.gonitropowder.com). Accessed August 13, 2019.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed August 13, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01.23.17	
Converted to new template. Minor changes to verbiage and grammar. References updated.	05.11.17	11.17
4Q 2018 annual review: no significant changes; references reviewed and updated.	08.21.18	11.18
4Q 2019 annual review: no significant changes; references reviewed and updated.	08.13.19	11.19

**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.

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