Clinical Policy Title:	nitroglycerin
Policy Number:	RxA.156
Drug(s) Applied:	GoNitro™
Original Policy Date:	02/07/2020
Last Review Date:	06/10/2021
Line of Business Policy Applies to:	All lines of business

Background

GoNitro™ is an organic nitrate that is a vasodilator which has effects on both arteries and veins. It is indicated for acute relief of an attack or prophylaxis of angina pectoris due to coronary artery disease.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
nitroglycerin (GoNitro™)	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. If chest pain persists after three packets, seek prompt medical attention. May be used prophylactically 5 to 10 minutes prior to engaging in activities that might precipitate an acute attack.	1,200 mcg within 15 minutes

Dosage Forms

- Sublingual powder: 400 mcg/packet

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by Rxadvance or member has previously met initial approval criteria listed in this policy.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
PDE-5: Phosphodiesterase type 5
sGC: Soluble Guanylate Cyclase

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

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 (PDE-5) inhibitors, such as avanafil, sildenafil, tadalafil, or vardenafil, or soluble guanylate cyclase (sGC) 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

APPENDIX D: General Information
Not Applicable

References

1. GoNitro™ Prescribing Information. Jacksonville, FL: Espero Pharmaceuticals, Inc.; August 2018. Available at: https://dailymed.nlm.nih.gov/dailymed/. Accessed February 19, 2021.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed February 19, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Clinical Policy Title was updated 2. Drug(s) Applied was updated 3. Line of Business Policy Applies to was updated 4. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." **5.** Commercial approval duration and Medicaid approval duration updated. 6. Updated APPENDIX A: Abbreviation/Acronym Key to include PDE-5: Phosphodiesterase type 5 and sGC: Soluble Guanylate Cyclase 7. References were updated	07/08/2020	09/14/2020
Policy was reviewed: 1. Last Review Date was updated. 2. Clinical policy verbiage was updated to “The provision of provider samples does not guarantee….”. 3. APPENDIX B: Therapeutic Alternatives verbiage was updated to "Below are suggested therapeutic alternatives based on clinical guidance....". 4. References were updated.	2/19/2021	06/10/2021