

POLICY AND PROCEDURE

POLICY NUMBER: *RX.PA.209.E*

REVISION DATE: *12/15*

PAGE NUMBER: 1 of 3

POLICY TITLE: *Rectiv (nitroglycerin ointment) 4%*
DEPARTMENT: *Clinical Pharmacy Services- Utilization Management*
ORIGINAL DATE: *September 2013 (as adopted from UPMC Health Plan)*

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	<input type="checkbox"/> HMO <input type="checkbox"/> PPO Products: <input type="checkbox"/> Small Exchange: <input type="checkbox"/> Shop <input checked="" type="checkbox"/> All <input type="checkbox"/> Indiv. <input type="checkbox"/> Indiv. <input type="checkbox"/> Large
OTHER	<input checked="" type="checkbox"/> Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Rectiv (nitroglycerin ointment).

Rectiv (nitroglycerin ointment) is indicated for the treatment of moderate to severe pain associated with chronic anal fissure.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Rectiv (nitroglycerin ointment), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must have a diagnosis of chronic anal fissure
- Must have an adequate trial and failure of conservative treatment through local wound care and relief of constipation
- Must not have any of the following contraindications:
 - Concomitant use of a phosphodiesterase type 5 (PDE5) inhibitor such as sildenafil (Revatio®, Viagra®), tadalafil (Adcirca®, Cialis®), vardenafil (Levitra®, Staxyn®)
 - Severe anemia (defined as hemoglobin <8g/dL)
 - Increased intracranial pressure

Reauthorization Criteria:

All prior authorization renewals are reviewed on a case-by-case basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon the following:

- Documentation of improvement in the condition based upon the prescriber's assessment while on treatment
- Clinical rationale for continuation of topical therapy versus surgery

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 month
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review.



REFERENCES

1. American Gastroenterological Association medical position statement: Diagnosis and care of patients with anal fissure. *Gastroenterology* 2003;124(1):233-234.
2. Berry S, Barish C, Bhandari R, et. al. Nitroglycerin 0.4% ointment vs. placebo in treatment of pain resulting from chronic anal fissure: a randomized, double-blind, placebo-controlled study. *Gastroenterology*. 2013;13:106.
3. Ezri T and Susmallian S. Topical nifedipine vs. topical glyceryl trinitrate for treatment of chronic anal fissure. *Dis Colon Rectum* 2003;46(6):805-808.
4. Knight J, Birks M, and Farouk R. Topical diltiazem ointment in the treatment of chronic anal fissure. *British Journal of Surgery* 2001;88:553-556.
5. Nelson R, Thomas, K, Morgan J, et. al. Non-surgical therapy for anal fissure. *Cochrane Database Syst Rev* 2012;2.
6. Rectiv [prescribing information]. Waltrip, Germany: Pharbil Waltrip GmbH; July 2013.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<i>Annual review</i>	<i>02/17, 02/18</i>

