



**BlueCross BlueShield
of Alabama**

Name of Policy:

Pulsed Irrigation Evacuation (PIE)

Policy #: 049
Category: DME

Latest Review Date: April 2009
Policy Grade: Active policy but no longer
scheduled for regular
literature reviews and update.

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
- 3. The technology must improve the net health outcome;*
- 4. The technology must be as beneficial as any established alternatives;*
- 5. The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- 1. In accordance with generally accepted standards of medical practice; and*
- 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
- 3. Not primarily for the convenience of the patient, physician or other health care provider; and*
- 4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

The pulsed irrigation evacuation (PIE) system has been used to treat chronic constipation and fecal impaction in patients with neurologic causes of altered bowel function, including quadriplegia, paraplegia, spinal cord injury, spina bifida, etc., and for bowel preparation for colonoscopy.

The PIE procedure uses pulses of small amounts of warm water to rehydrate stool and improve peristalsis. The system consists of a control unit to control inflow and outflow time and disposable supplies including a water reservoir bag, a cuffed speculum, and outflow bag into which the water and stool flows. This is a closed system to minimize fecal soiling and potential contamination.

Policy:

Effective for dates of service on or after April 1, 2003:

Pulsed irrigation meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage in patients with neuropathic bowel who have failed conservative techniques of bowel retraining, as evidenced by repeated episodes of impaction requiring physician intervention or hospitalization.

Pulsed irrigation meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage for treatment of fecal impaction in the hospital or outpatient setting.

Effective for dates of service prior to April 1, 2003:

Pulsed irrigation does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

There are a wide variety of causes of chronic constipation, including endocrine disorders (hypothyroidism), metabolic disorders, neurologic disorders (spinal cord lesions, multiple sclerosis), rheumatologic disorders, psychological disorders, and medications. The treatment includes correction of metabolic abnormalities, patient education to increase fluid and fiber intake and to exercise, fiber supplements, hyperosmolar laxatives, and possibly emollient or stimulant laxatives.

There are several published articles on the efficacy of PIE in the treatment of chronic constipation and fecal impaction in patients with neuropathic bowel. However, all of these are

uncontrolled case studies. There are no studies comparing PIE to a standard bowel regimen in patients with neurologic causes of altered bowel function.

There are also studies looking at PIE to cleanse the colon for colonoscopy. In 1991, Chang compared PIE (18 patients) vs. oral colonic lavage (15 patients) for colonoscopy prep and found no significant difference. In 2000, Ayub looked at 20 patients who had PIE prior to colonoscopy and all had acceptable or better results. There was no comparison between PIE prep and the traditional means. There is a larger study underway comparing Golysele colon prep with PIE prep.

In 2001, Nelson, et al, reviewed colonoscopy preparations. He stated the advantages of the pulsed irrigation for enhanced evacuation (PIEE) system included a short cleansing time and its use in patients unable to tolerate oral preparations or unable to ambulate to a commode. Disadvantages include the use of the nursing staff and extra space to perform the preparation and the cost of the equipment.

Patients with neuropathic bowel who had failed bowel-retraining methods are the primary focus for studies of pulsed irrigation as a treatment of fecal impaction. For example, Puet, et al, reported on 398 procedures performed at a rehabilitation hospital for patients with spinal cord injury or stroke. On three consecutive occasions the indications for the pulsed irrigation included symptomatic impaction, asymptomatic impaction with bowel distension and failure of a bowel routine to produce stool. Out of 246 procedures, 162 (66%) were performed on 4 patients, while 63 (41%) of the 152 inpatient procedures were performed on 31 spinal cord injury patients. There were only three cases where the procedure was not effective in removing stool. Two of the three patients could not tolerate the procedure because of previous strokes. The other patient had a spinal cord injury and could not retain the pulsed fluid. Kokoszka et al reported on the successful use of pulsed irrigation in 14 patients with fecal impaction who were considered candidates for hospitalization for disimpaction.

Key Words:

Pulsed irrigation evacuation (PIE)

Approved by Governing Bodies:

FDA approval as a Regulatory Class II device on September 11, 1986.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply

FEP contracts: FEP does not consider investigational. Will be reviewed for medical necessity

Pre-certification/Pre-determination requirements: Not applicable

Coding:

CPT coding:	91123	Pulsed irrigation of fecal impaction
HCPCS codes:	E0350	Control unit for electronic bowel irrigation/evacuation system
	E0352	Disposable pack (water reservoir bag, speculum, valving mechanism and collection bag/box) for use with the electronic bowel irrigation/evacuation system

References:

1. Ayub, K. et al. *Pulsed irrigation evacuation: A better technique for colon cleansing?*, Digestive Disease Week, April 2000, Part 2, Vol., 51, No. 4. (Abstract)
2. Borum, M. *Constipation: Evaluation and management*, Primary Care; Clinics in Office Practice, September 2001, Vol. 28, No. 3.
3. Chang, K.J., et al. *Per-rectal pulsed irrigation versus per-oral colonic lavage for colonoscopy preparation: A randomized, controlled trial*, Gastrointestinal Endoscopy, July-August 1991, Vol. 37(4); 444-8. (Abstract)
4. Gilger, M., et al. *New treatment for rectal impaction in children: An efficacy, comfort, and safety trial in the pulsed-irrigation enhanced-evacuation procedure*, Journal of Pediatric Gastroenterology and Nutrition, 1994, Vol. 18, No. 1.
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7. Lansang, R. *Bowel management*, <http://www.emedicine.com/pmr/topic230.htm>.
8. Nelson, D., et al. *Colonoscopy preparations*, Gastrointestinal Endoscopy, December 2001, Vol. 54, No. 6.
9. Puet, T.A., et al. *Pulsed irrigation enhanced evacuation: New method for treating fecal impaction*, Archives Physical Medicine Rehabilitation, October 1991; 72(11): 935-936. (Abstract)
10. Puet, T.A., et al. *Use of pulsed irrigation evacuation in the management of the neuropathic bowel*, Spinal Cord, 1997; 35: 694-699.

Policy History:

Medical Policy Group, December 2001

Medical Policy Group, April 2003 (3)

Medical Policy Administration Committee, April 2003

Available for comment May 19-July 2, 2003

Medical Policy Group, April 2006 (1)

Medical Policy Group May 2009: Active Policy but no longer scheduled for regular literature reviews and updates effective May 7, 2009

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date

hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.