Pulsed Irrigation of Fecal Impaction
Archived Medical Policy

Archived medical policies are no longer subject to periodic review, are maintained for reference, and may be returned to active status if the need is identified.

Policy # 00107
Original Effective Date: 03/25/2002
Archived Date: 04/19/2006

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services May be Eligible for Coverage
Note: Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met

Based on review of available data, the Company may consider pulsed irrigation as a treatment of fecal impaction in the hospital, outpatient, and clinic setting to be eligible for coverage.

Based on review of available data, the Company may consider chronic home use of a device for pulsed irrigation of fecal impaction 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 to be eligible for coverage.

Patient Selection Criteria
Coverage eligibility will be considered when all of the following criteria are met:

- Failure of conservative therapy for fecal impaction, defined as constipation requiring physician intervention or hospitalization; and
- Any condition that predisposes the patient to chronic constipation.

Background/Overview
Pulsed irrigation of fecal irrigation involves the use of a device consisting of a speculum inserted into the rectum and held in place with an inflatable cuff. Rapid pulses of water are then administered, which are intended to rehydrate dry, hard, impacted fecal material. It is also thought that the presence of the speculum and cuff and the vibration related to the pulsing water stimulate the autonomic system, similar to digital stimulation, thus promoting peristalsis, and further contributing to disimpaction. Pulsed irrigation may be performed in an inpatient setting, emergency room, physician’s office, or in the home.

Pulsed irrigation in the home setting has been primarily used in patients with a neuropathic bowel who have failed conservative therapy with bowel training. Bowel training focuses on establishing optimal fecal consistency and stimulation of peristalsis at regular intervals to develop a conditioned reflex to defecate. Stimulation of peristalsis may consist of use of suppositories, digital stimulation of the anal canal, or abdominal massage to increase the intra-abdominal pressure. Enemas may also be used, but these are frequently ineffective in those with spinal cord injury due to the lack of sphincter control. Fecal impaction, defined as constipation requiring physician intervention or hospitalization, represents a failure of conservative therapy.
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FDA or other Governmental Regulatory Approval
The device was cleared by the FDA based on a 510(k) application due to its substantial equivalence to pre-amendment devices. Hence, the manufacturer was not required to present clinical efficacy data to the FDA.

Rationale/Source
Studies of pulsed irrigation as a treatment of fecal impaction have primarily focused on patients with neuropathic bowel who had failed bowel retraining methods. For example, Puet et al reported on 398 procedures performed at a rehabilitation hospital for patients with spinal cord injury and stroke. The indications for the pulsed irrigation included symptomatic impaction, asymptomatic impaction with bowel distension, and failure of a bowel routine to produce stool on 3 consecutive occasions. Of the 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. The procedure was effective in removing stool in all but 3 of the cases; 2 of these patients were stroke patients who could not tolerate the procedure, while 1 patient was a spinal cord injury patient who could not retain the pulsed fluid. Kokoszka and colleagues reported on the successful use of pulsed irrigation in 14 patients with fecal impaction who were considered candidates for hospitalization for disimpaction.

References

Policy History
Original Effective Date: 03/25/2002
03/21/2002 Medical Policy Committee review
03/25/2002 Managed Care Advisory Council approval
06/24/2002 Format revision. No substance change to policy
03/02/2004 Medical Director review
03/16/2004 Medical Policy Committee review revision. No substance change to policy
03/29/2004 Managed Care Advisory Council approval
03/01/2005 Medical Director review
03/15/2005 Medical Policy Committee review
04/04/2005 Managed Care Advisory Council approval
04/05/2006 Medical Director review. Recommend archiving policy.
04/19/2006 Medical Policy Committee review. Archived.

Next Scheduled Review Date: Archived medical policy.

*Investigational – A medical treatment, procedure, drug, device, or biological product is investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:
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A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, according to the consensus of opinion among experts as shown by reliable evidence, including:
   1. consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other non-affiliated technology evaluation center(s);
   2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
   3. reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:
A. in accordance with nationally accepted standards of medical practice;
B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and 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.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.