Enemeez® & *Enemeez*® Plus:

Pilot Study Quick Reference Sheet

Objective:

This Pilot Study is to offer ***Enemeez***® as an alternative to repetitive stimulant laxatives and large volume enemas in selected patients and determine the impact on nursing/CNA time, patient satisfaction, and side effects.

Start Date: (TBD)
End Date: (TBD)
Pilot Study Duration: Four to eight weeks.

Advantages to Facility:

- **Financial**- ***Enemeez***® is relatively similar to bisacodyl suppositories in product pricing. The goal of the pilot study is to determine the amount of reduced nursing and CNA intervention time required for prolonged bowel care, as well as the significant ancillary advantages, such as work efficiency and staff satisfaction. Included in this are: savings on the reduced use of chuck pads, and gown and laundry services needed - due to the reduction of episodes of incontinence and mucosal discharge associated with bisacodyl-based suppositories. Ineffective laxative therapy may result in additional use of facility resources. Incontinence and mucosal discharge increases the pH of the skin, and may result in loss of skin integrity, incontinence-associated dermatitis, or even pressure ulcers.
- **Workplace Satisfaction and Staff Turnover**- Subjective assessment by nursing and CNAs. The results will be used to gauge internal satisfaction addressing this chronic problem, and the resulting staff turnover.
- **Improved Quality**- Given ***Enemeez***® is not being used as first line at your facility, its innovative use will lead to improvements in skilled care and QI within the facility.

Pilot Measures and Expectations:

1. Time spent from insertion of ***Enemeez***® to completion of bowel care.
2. Did patient experience Autonomic Dysreflexia?
3. Number of episodes of incontinent stools or accidents.
4. Number of episodes of mucosal discharge. * PLEASE NOTE: the Important Prior Patient Laxative Usage Notification contained within the pilot study chart.
5. Time spent providing digital stimulation by nursing staff.
6. Length of time spent by nursing staff on cleaning/ changing patient due to incontinence.
7. Number of times and length of time incontinence interrupted rehabilitation, physical therapy etc.
8. Additional pads and clothing that were required to be used due to an incontinence episode.
9. Overall nursing/CNA staff satisfaction, ease of use, and patient satisfaction.

Patient Base:

A minimum of 20 patients during a four or eight week period is suggested by the manufacturer.

Pre-Trial Patient Evaluation and Proficiency:

A pre-trial patient evaluation should be completed and charted prior to admitting patient into pilot study. The pre-trial evaluation form is provided within your pilot study packet. Evaluation shall contain:

1. Identification of patient's bowel care regimen prior to stay at facility.
2. Complications with current bowel care regimen while at the facility.
3. Prior four weeks laxative usage.
4 . Evaluate skin care quality issues.
5. Number of episodes of incontinence during previous four weeks.
6. Length of time lost in rehab due to incontinence episodes from the prior four weeks.
7. Prior four weeks average length of time per week spent on bowel care needs.

Patient Criteria:

1. Has been evaluated and scored on the MDS 3.0 Section H.
2. Patient is at least 18 years of age.
3. Speaks English or can communicate with healthcare provider.
4. Inpatient at your facility for the 4-8 week pilot study.
5. Patient has signed consent form to participate in the pilot study.

Patient meets one or more of the following:

1. Has a need basis for a regulated bowel care regimen.
   a. Has had one impaction in the last 30 days.
   b. Consistently needs further intervention after administered oral therapy.
   c. Does not evacuate without intervention.
   d. Consistently requires Level 3 protocol laxative therapy, further followed by episodes of diarrhea.
   e. Has a spinal cord injury or is a MS patient.
   f. Patient suffers with Neurogenic Bowel.
2. High narcotic use for pain management.

Important Prior Patient Laxative Usage Notification:

Enemeez® should be trialed on a patient prior to the use of bisacodyl. If patient has been using a bisacodyl product, please keep in mind that bisacodyl is a stimulant laxative that irritates the rectal mucosa, and neutrophils can persist in the mucosa for up to 30 hours after insertion of the bisacodyl.[1]

This mucosal discharge may occur for up to three (3) days after discontinuing bisacodyl. The trial should reflect the healing time needed on the rectal mucosa from the use of the bisacodyl product in order to produce an accurate recording of the effects of ***Enemeez***®. With older patients, please allow at least five (5) bowel sessions for the body to acclimate to ***Enemeez***®.

Enemeez® Does **NOT** produce a mucosal discharge. Do not use in conjunction with mineral oil.

Baseline Data Collection Process:

1. Weekly data collection is to be sent to designated facility contact.
2. Final collection, compilation, and study determination.
3. Post-pilot briefing with facilities on outcomes and data.

Enemeez® | *Enemeez*® *PLUS* Product Description:

Enemeez® is a 5mL mini-enema containing 283mg of docusate sodium in a polyethylene glycol and glycerine base. ***Enemeez***® was designed for bowel care programs associated with spinal cord injuries and disease.

Enemeez® ***PLUS*** contains 20mg of benzocaine, assisting in the anesthetization of the rectum and lower bowel. This formulation was developed for patients who experience painful bowel movements.

Products that *Enemeez*® would replace include:

- Glycerine Suppository
- Bisacodyl Suppository
- Enemas - Large volume or bisacodyl enemas
- Tap water enemas

How *Enemeez*® Works:

The ***Enemeez***® formulation functions as a stool softening hyper-osmotic laxative by drawing water into the bowel from surrounding body tissues. The docusate sodium acts as a softener by preparing the stool to readily mix with watery fluids. The increased mass of stool promotes a bowel evacuation by stimulating nerve endings in the bowel lining and initiating peristalsis. Not only does it soften and loosen the stool, but it initiates a normal stimulus replicating a normal bowel movement. ***Enemeez***® generally produces a bowel movement in 2-15 minutes.[2]

Ordering Information:

National Drug Code Numbers

Enemeez®	**17433-9876-03**
Enemeez® **Plus**	**17433-9877-03**

Positioning:

For best results, lay on left side with knees bent. Insert slowly into rectum, up to shoulder of tube.
Alternate positions:

- Administer while seated on the toilet.
- Or, kneel, then lower head and chest forward until side of face is resting on the surface.

Administration:

Adults and children 12 years and older (with adult supervision). Children under 12 years of age, consult a doctor prior to use.

1. Clear stool from the rectal opening, as you do not want to insert directly into feces.
2. Twist off and remove tip.
3. Lubricate tip prior to insertion. Place a few drops of the tube's liquid content on the shaft prior to insertion.
4. Also, apply liquid content or lubricant to the anus before inserting the mini-enema tube.
5. With steady pressure, gently insert the tube into the rectum with care to prevent damage to the rectal wall. Insert up to the shoulder of the tube.
6. Squeeze to empty the contents.
7. Keep the tube squeezed until it is removed from the rectum.
8. After the contents have been emptied, remove the disposable tube and discard. A small amount of liquid may remain in the unit after use.

If no evacuation occurs after a 15 minute period, some patients may require digital stimulation to assist in bringing down the stool.

Warnings:

For rectal use only. Drug Interaction Precaution:
Do not take this product if you are presently taking mineral oil, unless directed by a doctor.

Do not use:

- Laxative products when abdominal pain, nausea or vomiting are present.
- Laxative products for a period longer than 1 week unless directed by a doctor.

Stop use and ask a doctor if you have:

- Rectal bleeding.
- Noticed a sudden change in bowel habits that persists over a period of 2 weeks.
- Failed to have a bowel movement after use. This may indicate a serious condition.

Pregnant or Lactating Women, ask a health professional before use.
Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

 1. Morphological consequences of bisacodyl on normal human rectal mucosa: effect of a prostaglandin E1 analog on mucosal injury, D. R. Saunders, MD, R. C. Haggitt, MD,M. B. Kimmey, MD, F. E. Silverstein, MD, VOLUME 36, NO.2, 19902. Source: 2. Federal Register / Vol. 50, No. 10 / Tuesday, January 15, 1985 / Proposed Rules; pg's 2124-2158. ENZ034 04.08.19

Pre-Evaluation Form

Patient Criteria:

- ☐ Patient is at least 18 years of age
- ☐ Speaks English or is able to communicate with a healthcare provider
- ☐ Inpatient at your facility for the 4-8 week pilot study, as determined by the facility
- ☐ Has signed consent to participate in Pilot

Active Disease Diagnosis

Neurological

- ☐ Alzheimer's Disease
- ☐ Aphasia
- ☐ Cerebral Palsy
- ☐ CVA / TIA / Stroke
- ☐ Hemiplegia / Hemiparesis / Paraplegia / Quadriplegia
- ☐ Multiple Sclerosis
- ☐ Parkinson's Disease
- ☐ Seizure Disorder
- ☐ Traumatic Brain Injury
- ☐ Other Neurological: enter diagnosis and ICD-10 _____

Health Conditions

Pain Management: (answer for all residents, regardless of current pain level) At any time in the last 5 days, has the resident:

a. Been on a scheduled pain medication regimen?

- ☐ No
- ☐ Yes

b. Received PRN pain medications?

- ☐ No
- ☐ Yes

Bladder & Bowel

Urinary Appliances: Check all that applied in the last 5 days:

- ☐ Indwelling bladder catheter
- ☐ External (condom) catheter
- ☐ Ostomy (suprapubic catheter, ileostomy)
- ☐ Intermittent catheterization
- ☐ None of the above

Urinary Continence: Urinary continence in the last 5 days. Select the one category that best describes the resident over the last 5 days:

- ☐ Always continent
- ☐ Occasionally incontinent (less than 5 episodes of incontinence)
- ☐ Frequently incontinent (5 or more episodes of incontinence but at least one episode of continent voiding)
- ☐ Always incontinent (no episodes of continent voiding)
- ☐ Not rated, resident had a catheter (indwelling, condom), urinary ostomy, or no urine output for the entire 5 days

Bowel Continence: Bowel continence in last 5 days. Select the category that best describes the resident over the last 5 days:

- ☐ Always continent
- ☐ Occasionally incontinent (less than 5 episodes of bowel incontinence)
- ☐ Frequently incontinent (5 or more episodes of bowel incontinence but at least one episode of continent bowel movement)
- ☐ Always incontinent (no episodes of continent bowel movements)
- ☐ Not rated, resident had an ostomy or did not have a bowel movement for the entire 5 days

Bowel Patterns:

- ☐ Has had one impaction in last 30 days
- ☐ Consistently needs further intervention after administered oral therapy
- ☐ Does not evacuate without intervention
- ☐ Consistently requires Level 3 protocol laxative therapy, further followed by episodes of diarrhea

Constipation: constipation present in the past 5 days?

- ☐ No
- ☐ Yes

Current Bowel Care Medications:

- ☐ Oral Laxative
- ☐ Enema - Large volume or bisacodyl enemas
- ☐ Tap Water Enema
- ☐ Bisacodyl Suppository
- ☐ Glycerine Suppository

How often are rectal therapies used?

- ☐ Daily
- ☐ Every other day
- ☐ Every third day
- ☐ PRN

List complications with current bowel program: _____

Nursing time in Hr / Min required for bowel care

____/____ Average daily time spent with patient by nursing staff for bowel care needs

Missed Rehabilitation time in Hr / Min

____/____ Missed rehabilitation time due to incontinence in the last five days.

____/____ Missed rehabilitation time due to constipation bowel care needs in the last five days.

Skin Conditions

1. Current Pressure Ulcer: Did the resident have a pressure ulcer in the last 5 days?

- ☐ No (healed pressure ulcers)
- ☐ Yes

2. Identify the stage and current number of Pressure Ulcers: Indicate the number of current pressure ulcers that were present prior to beginning pilot study (if no current pressure ulcer at a given stage, enter 0).

☐ **Check here if N/A (no prior assessment)**

Enter # ☐ **a. Stage 1**- Observable pressure-related alteration of an area of intact skin whose indicators may include change in skin temperature (warm or cool), tissue consistency (firm or boggy feel), or sensation (pain, itching). In lightly pigmented skin, appears as an area of persistent redness. In darker skin tones, may appear with persistent red, blue, or purple hues.

Enter # ☐ **b. Stage 2**- Partial thickness skin loss involving epidermis, dermis, or both. The ulcer presents clinically as an abrasion, blister, or shallow crater.

Enter # ☐ **c. Stage 3**- Full thickness skin loss involving damage to, or necrosis of, subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.

Enter # ☐ **d. Stage 4**- Full thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures (e.g. tendon, joint, capsule). Undermining and sinus tracts also may be associated with Stage 4 pressure ulcers.