MedStar Family Choice		
ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**1404**	
Subject:	**INTERSTIM® for Fecal Incontinence**	
Section:	**Medical Non-Pharmacy Protocols**	
Initial Effective Date:	**10/01/2011**	
Revision Effective Date(s):	**07/18, 07/19, 07/20, 07/21, 07/22, 07/23**	
Historical Revision Date(s):	**12/12, 10/13, 10/14, 07/17**	
Review Effective Date(s):		
Historical Review Date(s):	**10/15, 10/16**	
Responsible Parties:	**Inna Kats, M.D.**	
Responsible Department(s):	**Clinical Operations**	
Regulatory References:	**N/A; see references below**	
Approved:	**Carol Attia, MBA, BSN, RN** **VP Clinical Care and Quality**	**Karyn Wills, MD** **Chief Medical Officer**

Purpose: **To define the process for the Prior Authorization of INTERSTIM implantable Sacral Nerve Stimulator for treatment of chronic fecal incontinence for members of MedStar Family Choice (MFC).**

Scope: **MedStar Family Choice, Maryland**

Policy: **It is the policy of MFC to provide INTERSTIM therapy to appropriate members of MFC who meet the authorization criteria below.**

Background:

A. MedStar Family Choice will require prior authorization for the INTERSTIM sacral nerve stimulation system for bowel incontinence. Authorization will be given for FDA-approved indications (The FDA has already approved this device for urinary incontinence).

B. INTERSTIM is currently approved by the FDA for the following indication(s):
   1. Chronic fecal incontinence when the following conditions are met:
      a. Chronic fecal incontinence of greater than 2 incontinent episodes on average per week with duration greater than 6 months or for more than twelve months after vaginal childbirth; and

b. Documented by detailed medical records showing exactly what treatments have been tried and for how long, failure or intolerance to conventional therapy (e.g., dietary modification, the addition bulking and pharmacologic treatment) for at least a sufficient duration to fully assess its efficacy,
c. The patient is an appropriate surgical candidate; and
d. A successful percutaneous test stimulation, defined as at least 50% improvement in symptoms, was performed; and
e. The condition is not related to an anorectal malformation (e.g., congenital anorectal malformation; defects of the external anal sphincter over 60 degrees; visible sequelae of pelvic radiation; active anal abscesses and fistula) or chronic inflammatory bowel disease or constipation/ constipation treatment and
f. Incontinence is not related to another neurologic condition such as peripheral neuropathy or complete spinal cord injury.

C. Limitations

Sacral nerve modulation/stimulation is considered **experimental, investigational and unproven for the treatment of chronic constipation or chronic pelvic pain.**

Procedure:

1. Requests for INTERSTIM for fecal incontinence therapy will be processed in accordance with MedStar Family Choice Policy 110; UM Process.

2. Requests for off-label use of INTERSTIM for fecal incontinence may be submitted to a Medical Director for individual consideration.

References:

1. Local Coverage Article #A55835
https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55835&ver=10&keyword=A55835&keywordType=starts&areaId=all&docType=NCA%2cCAL%2cNCD%2cMEDCAC%2cTA%2cMCD%2c6%2c3%2c5%2c1%2cF%2cP&contractOption=all&sortBy=relevance&bc=AAAAAAQAAAAA&KeyWordLookUp=Doc&KeyWordSearchType=Exact

Summary of Changes:	**07/23:** • Updated approved by to Carol Attia and Dr. Wills • **C**larified indications for coverage • **A**dded limitation • **U**pdated link to reference **07/22:** • Removed NCQA from Regulatory References. • Updated responsible party from Dr. Toye to Dr. Kats. • Formatted reference section. **07/21:** • Updated Regulatory References to reflect 2021 NCQA Standards. • Added "Maryland" to scope.

	• Updated references. • Updated Responsible Departments from Utilization Management to Clinical Operations. **07/20:** • Updated Section from Care Management to Medical Non-Pharmacy Protocols. • Updated Regulatory References to reflect 2020 NCQA Standards. **07/19:** • Updated NCQA Reference to reflect 2019 Standards. • Removed "Maryland" from scope. • Removal of "A" from policy number. **07/18:** • Removed references to DC health plans. • Updated reference. • Modified Effective Date to Initial Effective Dates; added Historical Revision Dates and Revision Effective Dates; and added Historical Review Dates and Review Effective Dates. **07/17:** • Added citation for UM Process Policy 110 A & B. **10/16:** • Added regulatory reference. **10/15:** • No changes.