MedStar Family Choice DISTRICT OF COLUMBIA		
ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**1404.DC**	
Subject:	**INTERSTIM® for Fecal Incontinence**	
Section:	**Medical Non-Pharmacy Protocols**	
Initial Effective Date:	**10/01/2020**	
Revision Effective Date(s):	**07/21, 07/22, 07/23, 07/24, 0/7/25**	
Review Effective Date(s):		
Responsible Parties:	**Medical Director**	
Responsible Department(s):	**Clinical Operations**	
Regulatory References:	**Medicare Local Coverage Article; see references below**	
Approved:	**Director, Clinical Operations**	**Senior Medical Director 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 Enrollees of MedStar Family Choice District of Columbia.**

Scope: **MedStar Family Choice District of Columbia**

Policy: **It is the policy of MedStar Family Choice DC to provide INTERSTIM therapy to appropriate Enrollees of MedStar Family Choice DC who meet the authorization criteria below.**

Background:

A. MedStar Family Choice DC 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; 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 other neurologic conditions 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 can be approved by nurse clinical operations staff if the above FDA criteria are met

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

References:

Local Coverage Article #A55835
https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55835&ver=15&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:	**07/25:** • Updated References Links • Clarified indications for coverage • Added limitation **07/24:** • Updated Responsible Parties to include only position titles and not names. **07/23:** • Reviewed and updated the reference. • Updated MFC to MFC-DC throughout document. **07/22:** • Updated Responsible Parties. • Updated Approved.

	• Updated regulatory references to reflect NCQA 2022. **07/21:** • Updated Regulatory References to reflect 2021 NCQA Standards. • Removed citation for UM Process Policy #110 and replaced it with reference to FDA criteria. • Updated Reference link. **10/20:** • New policy.