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:	**10/2020**	
Revision Effective Date(s):	**07/21**	
Review Effective Date(s):	**07/22**	
Responsible Parties:	**Medical Director**	
Responsible Department(s):	**Clinical Operations**	
Regulatory References:		
Approved:	**Sharon Henry, RN Director, Clinical Operations**	**Reymond Tu, MD Senior Medical Director (CMO)**

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 (MFC).**

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

Policy: **It is the policy of MFC to provide INTERSTIM therapy to appropriate enrollees 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; and
        b. Documented 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; and
f. Incontinence is not related to other neurologic conditions such as peripheral neuropathy or complete spinal cord injury.

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/details/article-details.aspx?articleid=55835&ver=7&keyword=A55835&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=AAAAAAQAAAAA&KeyWordLookUp=Doc&KeyWordSearchType=Exact

Summary of Changes:	**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.