

## ADMINISTRATIVE POLICY AND PROCEDURE

<b>Policy #:</b>	<b>1404.DC</b>	
<b>Subject:</b>	<b>INTERSTIM® for Fecal Incontinence</b>	
<b>Section:</b>	<b>Medical Non-Pharmacy Protocols</b>	
<b>Initial Effective Date:</b>	<b>10/01/2020</b>	
<b>Revision Effective Date(s):</b>		
<b>Review Effective Date(s):</b>		
<b>Responsible Parties:</b>	<b>Inna Kats, MD</b>	
<b>Responsible Department(s):</b>	<b>Clinical Operations</b>	
<b>Regulatory References:</b>	<b>NCQA 2020: UM 2C</b>	
<b>Approved:</b>	<b>Sharon Henry, RN Director, Clinical Operations</b>	<b>Patryce A. Toye, MD Chief Medical Officer</b>

**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 another neurologic condition such as peripheral neuropathy or complete spinal cord injury.

**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 uses 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=6&Keyword=Sacral%20Nerve%20Stimulation&KeywordLookup=Title&KeywordSearchType=Exact&bc=CAAAAAAAAAAAAA>

<b>Summary of Changes:</b>	<b>10/20:</b> <ul style="list-style-type: none"> <li>• New policy.</li> </ul>
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