



**ADMINISTRATIVE POLICY AND PROCEDURE**

<b>Policy #:</b>	<b>1404</b>	
<b>Subject:</b>	<b>INTERSTIM® for Fecal Incontinence</b>	
<b>Section:</b>	<b>Care Management</b>	
<b>Effective Date:</b>	<b>10/01/2011</b>	
<b>Revision Date(s):</b>	<b>12/12, 10/13, 10/14</b>	
<b>Review Date(s):</b>	<b>10/15, 10/16</b>	
<b>Responsible Parties:</b>	<b>Patryce Toye, MD</b>	
<b>Responsible Department(s):</b>	<b>Utilization Management</b>	
<b>Regulatory References:</b>	<b>MD Delmarva 2016: 7.2 NCQA 2016: UM 2C</b>	
<b>Approved:</b>		
	<b>Carol Attia, RN AVP, Care Management</b>	<b>Patryce A. Toye, MD Senior Medical Director</b>

**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, MD; MedStar Family Choice, District of Columbia Healthy Families and Alliance.

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

**Background:** 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)

INTERSTIM is currently approved by the FDA for the following indication(s):

Chronic fecal incontinence when the following conditions are met:

- Chronic fecal incontinence of greater than 2 incontinent episodes on average per week with duration greater than 6 months; AND

- 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,
- The patient is an appropriate surgical candidate; AND
- A successful percutaneous test stimulation, defined as at least 50% improvement in symptoms, was performed; AND
- 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
- Incontinence is not related to another neurologic condition such as peripheral neuropathy or complete spinal cord injury.

**Procedure:**

- A. Requests for INTERSTIM for fecal incontinence therapy should be forwarded along with the supporting clinical information to QRM in accordance with the MedStar Family Choice Prior Authorization Policy.
1. MFC will request clinical records, laboratory results or other information as part of the prior authorization process.
  2. If the Physician Advisor needs additional clinical information, MFC Preauthorization staff will make a specific request from the prescribing provider.
  3. MFC will make three attempts to obtain requested clinical information.
  4. A decision will be rendered by the Physician Advisor within 2 business days of receipt of the complete clinical information and no later than 7 days after the receipt of the original request in accordance with COMAR 10.09.71.04 and so as to not adversely affect the health of the enrollee.
- B. Requests for off-label uses of INTERSTIM for fecal incontinence may be submitted to the Medical Director of MedStar Family Choice for individual consideration.

<b>Summary of Changes:</b>	<p><b>10/16:</b></p> <ul style="list-style-type: none"> <li>• Added regulatory reference</li> </ul> <p><b>10/15:</b></p> <ul style="list-style-type: none"> <li>• No changes</li> </ul>
----------------------------	---