

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	
Review Effective Date(s):		
Responsible Parties:	Medical Director	
Responsible Department(s):	Clinical Operations	
Regulatory References:	Medicare LCD	
Approved:	AVPClinical Operations	Senior Medical Director (Chief Medical Officer-DC)

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 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://localcoverage.cms.gov/mcd_archive/view/article.aspx?articleInfo=55835:7
<https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=55835&ver=14>
 Accessed: 05/21/2024

Summary of Changes:	<p>07/24:</p> <ul style="list-style-type: none"> • Updated Responsible Parties to include only position titles and not names. <p>07/23:</p> <ul style="list-style-type: none"> • Reviewed and updated the reference. • Updated MFC to MFC-DC throughout document. <p>07/22:</p> <ul style="list-style-type: none"> • Updated Responsible Parties. • Updated Approved. • Updated regulatory references to reflect NCQA 2022. <p>07/21:</p> <ul style="list-style-type: none"> • 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. <p>10/20:</p> <ul style="list-style-type: none"> • New policy.
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