GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

DESCRIPTION
Fecal incontinence is the involuntary loss of flatus, liquid or stool from the rectum and anal canal. Severe fecal incontinence is a distressing and socially isolating medical condition.

A dynamic rectal control system is a prescription device intended to treat fecal incontinence by controlling the size of the rectal lumen. In November 2015, Pelvalon was granted by the U.S. FDA De Novo Reclassification request process to market the Eclipse System, the first vaginal insert designed to provide bowel control, in the United States. The Eclipse System is an innovative non-surgical therapy that offers immediate result for women experiencing loss of bowel control. The device is inserted in the vagina and includes a portion that expands to reduce the rectal lumen to prevent stool leakage and retracts to allow normal passage of stool. The device includes an inflatable balloon, which is placed in the vagina. When a trip to the bathroom is needed, the device is deflated and then re-inflated using an external pump. The eclipse is initially fitted and inflated by a trained clinician, following which the patients can control it themselves.

POLICY
HMO, PPO, Individual Marketplace, Elite, Advantage
Dynamic rectal control system (i.e., Eclipse System) (A4563) as a treatment for fecal incontinence is considered experimental/investigation, noncovered, because its effectiveness for this indication has not been established.

Procedures 46999 and 58999 are noncovered when related to the treatment of Rectal Control System for Fecal Incontinence (Eclipse)

HMO, PPO, Individual Marketplace, Elite, Advantage
Dynamic rectal control system (i.e., Eclipse System) (A4563) as a treatment for fecal incontinence is considered experimental/investigation, noncovered, because its effectiveness for this indication has not been established.

Claims for services involving the eclipse system should be billed with Current Procedural Terminology (CPT®) code 58999 (Unlisted procedure, female genital system) and Healthcare Common Procedure Coding System (HCPCS) code A4335 (incontinence supply, miscellaneous).

CODING/BILLING INFORMATION
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODE
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>46999</td>
<td>Unlisted procedure, anus (noncovered when related to the treatment of Rectal Control System for Fecal Incontinence (Eclipse))</td>
</tr>
<tr>
<td>58999</td>
<td>Unlisted procedure, female genital system (nonobstetrical) (noncovered when related to the treatment of Rectal Control System for Fecal Incontinence (Eclipse))</td>
</tr>
<tr>
<td>A4563</td>
<td>Rectal control system for vaginal insertion, for long term use, includes pump and all supplies and accessories, any type each</td>
</tr>
</tbody>
</table>

REVISION HISTORY EXPLANATION

REFERENCES/RESOURCES
Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid http://jfs.ohio.gov/