



## *Solesta*<sup>®</sup>

<b>Origination:</b> 08/15/12	<b>Revised:</b> 09/01/17	<b>Annual Review:</b> 11/02/17
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### **Purpose:**

- To provide guidelines for the Medical Department staff to reference when making benefit determinations.
- The Medical Technology Assessment Committee will review published scientific literature and information from appropriate government regulatory bodies (when available) related to Solesta<sup>®</sup> in order to determine inclusion in the benefit plan.

### **Recommendation:**

A recommendation was made by the MTAC following discussion by committee members based on current literature:

### ***Compliance Status***

- This procedure is in compliance with current *Food & Drug Administration* requirements

### ***Definitions***

- Solesta<sup>®</sup> is indicated for the treatment of fecal incontinence in Members who have failed conservative therapy (e.g., diet, fiber therapy and anti-motility medications). Solesta<sup>®</sup> consists of dextranomer microspheres, 50mg/ml, and stabilized sodium hyaluronate, 15mg/ml, in phosphate-buffered 0.9% sodium chloride solution. Solesta<sup>®</sup> is a biocompatible bulking agent in a disposable 1ml syringe. Solesta<sup>®</sup> is provided as a carton containing four (4) pouches with syringes. The product is for single use. A total of four (4) submucosal injections of 1ml are administered at each treatment session.
- Solesta<sup>®</sup> is injected into the deep submucosal layer in the proximal part of the high pressure zone of the anal canal about 5mm above the dentate line.

### ***Coverage Guideline***

- Member must be 18 years of age or older.



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### **Recommendation, continued:**

#### *Exclusion Criteria*

- Members with active inflammatory bowel disease.
- Members with immunodeficiency disorders or ongoing immunosuppressive therapy
- Members with previous radiation treatment to the pelvic area.
- Members with significant mucosal or full thickness rectal prolapse.
- Members with active anorectal conditions, including abscess, fissures, sepsis, bleeding, proctitis, or other infections.
- Members with anorectal atresia, tumors, stenosis or malformation.
- Members with rectocele.
- Members with rectal varices.
- Members with an existing implant (other than Solesta<sup>®</sup>) in the anorectal region.
- Members with a hypersensitivity to hyaluronic acid based products.

### **Procedure:**

- 1.0 Request for initial procedure with Solesta<sup>®</sup> requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying **ALL** of the following:
  - 1.1 Member has failed all conservative treatment options including:
    - 1.1.1 Dietary changes; AND
    - 1.1.2 Fiber therapy; AND
    - 1.1.3 Anti-motility medications including hyoscyamine and antidiarrheals;
  - 1.2 Procedure must be performed by a gastroenterologist in an ambulatory setting;
  - 1.3 If criteria are met, procedure may be approved one (1) time.

### **Reference:**

1. Solesta<sup>®</sup> package insert, Oceana Therapeutics, Inc. Edison, NJ 08817, June 2011.



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**Disclaimer Information:**

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed to determine coverage for AvMed's benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed makes coverage decisions using these guidelines, along with the Member's benefit document. The use of this guideline is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed for selected therapeutic or diagnostic services found to be safe, but proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the AvMed service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations.

Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change.