

SOLESTA (Dextranomer and hyaluronic acid)

Effective Date: 1/28/14

Date Developed: 1/28/14 by Robert Sterling, MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19, 2/18/20,

2/2/21, 8/3/21, 2/1/22, 1/31/23

Solesta is administered submucosally in the anal canal as a bulking agent in the anal area for patients with fecal incontinence who have failed to respond to more conservative therapies (e.g. diet, fiber therapy, antimotility agents, other bulking agents, temporary rectal tubes). Dextranomer is a network of dextran-sucrose beads which swell upon application; hyaluronate provides viscosity and facilitates injection.

Authorization:

Adult patients who have failed conservative therapies for fecal incontinence Pediatric patients with vesicoureteral reflux II to IV

Dosing: Refer to product labeling for detailed instructions

NOTE: Requires a person trained in its administration

PRECAUTIONS: hypersensitivity to hyaluronic acid; active inflammatory bowel disease; prior pelvic radiation; rectal prolapse; any active anorectal condition (e.g. abscess, fissure, hemorrhoids, bleeding);

DRUG INTERACTIONS: none known

REFERENCES

SOLESTA [package insert]. Edison, NJ: Oceana Therapeutics (US), Inc; 2011.

SOLESTA [package insert]. Raleigh, NC: Salix Pharmaceuticals, Inc; 2011.

Schwandner O, Brunner M, Dieti O. Quality of life and functional results of submucosal injection therapy using dextranomer hyaluronic acid for fecal incontinence. *Surg Innov.* 2011;18(2):130-135.

Hoy, SM (2012 Aug 20). "Dextranomer in stabilized sodium hyaluronate (Solesta®): in adults with faecal incontinence.". *Drugs* **72** (12): 1671–8.

Al Samarrai NR, Uman GC, Al-Samarrai T, Alessi CA. Introducing a new incontinence management system for nursing home residents. *J Am Med Dir Assoc.* 2007;8(4):253-261.

Xu X, Menees SB, Zochowski MK, Fenner DE. Economic cost of fecal incontinence. *Dis Colon Rectum.* 2012;55(5):586-598.

Rey E, Choung RS, Schleck CD, Zinsmeister AR, Locke GR 3rd, Talley NJ. Onset and risk factors for fecal incontinence in a US community.

Revision History:

Date Reviewed/No Updates: 1/13/15 by C. Sanders, MD

Date Approved by P&T Committee: 1/27/15

Date Reviewed/No Updates: 1/26/16 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/26/16

Date Reviewed/No Updates: 1/24/17 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/24/17

Date Reviewed/No Updates: 1/22/19 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/22/19

Date Reviewed/No Updates: 2/18/20 by H. Taekman, MD; R. Sterling, MD

Date Approved by P&T Committee: 2/18/20

Date Reviewed/No Updates: 2/2/21 by H. Taekman, MD; R. Sterling, MD

Date Approved by P&T Committee: 2/2/21

Date Reviewed/Updated: 8/3/21 by H. Taekman, MD; R. Sterling, MD

Date Approved by P&T Committee: 8/3/21

Date Reviewed/No Updates: 2/1/22 by H. Taekman, MD; R. Sterling, MD

Date Approved by P&T Committee: 2/1/22

Date Reviewed/No Updates: 1/31/23 by H. Taekman, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/31/23

Revision	Content	Contributors	Review/Revision
Date	Revised		Notes

	(Yes/No)		
1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/22/19	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
2/18/20	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/2/21	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
8/3/21	Yes	Howard Taekman, MD; Robert Sterling, MD	Minor Changes
2/1/22	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
1/31/23	No	Howard Taekman, MD; Robert Sterling, MD	Annual review