# PROVIDER POLICIES & PROCEDURES

## TREATMENT OF FECAL INCONTINENCE: HYALURONIC ACID/DEXTRANOMER GEL FOR SUBMUCOSAL INJECTION (SOLESTA®)

The primary purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP) with the information needed to support a medical necessity determination for Solesta®. By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

Fecal incontinence is the involuntary loss of bowel control caused by nerve damage, a weakened anal sphincter, or rectal muscle damage. Solesta® is a sterile gel that is injected into the layer of tissue beneath the lining of the anus. Solesta® is believed to work by building or "bulking" up tissue in the anal area thereby narrowing the anal opening resulting in a more adequate closure of the muscles. Typically there are four (4) injections of Soelsta® during each treatment.

### CLINICAL GUIDELINE

Coverage guidelines for Solesta® are made in accordance with the Department of Social Services (DSS) definition of Medical Necessity. The following criteria are guidelines *only.* Coverage determinations are based on an assessment of the individual and his or her unique clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:

The use of Solesta® is typically considered experimental and investigational and therefore not medically necessary for the treatment of fecal incontinence due to insufficient evidence of therapeutic value.

NOTE: EPSDT Special Provision
Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

### PROCEDURE

Prior authorization is required for both the surgical procedure (injection) and injectable gel (Solesta®). Requests for coverage will be reviewed in accordance with procedures in place for reviewing requests for medical-surgical services. Coverage determinations will be based upon a review of requested and/or submitted case-specific information.

**The following information is needed to review requests for Solesta®:**

1. Fully completed Outpatient Prior Authorization Request Form or fully completed authorization request via on-line web portal;
2. Documentation from the medical record supporting the medical necessity of the requested treatment;
3. Pricing information supporting the cost of the injectable gel (manufacturer's invoice); and
4. Other information as requested.

**EFFECTIVE DATE**

This Policy is effective for prior authorization requests for Solesta® for individuals covered under the HUSKY Health Program beginning December 1, 2014.

**LIMITATIONS**

N/A

**CODES:**

| Code | Description |
|---|---|
| 46999 | Unlisted procedure, anus |
| 99070 | Supplies and materials (except spectacles), provided by the physician or other qualified health care professional over and above those usually included with the office visit or other services rendered (list drugs, trays, supplies, or materials provided) |

**DEFINITIONS**

1. **HUSKY A**: Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.
2. **HUSKY B**: Uninsured children under the age of 19 in higher income households may be eligible for HUSKY B (also known as the Children's Health Insurance Program) depending on their family income level. Family cost-sharing may apply.
3. **HUSKY C**: Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.
4. **HUSKY D**: Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
5. **HUSKY Health Program**: The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
6. **HUSKY Limited Benefit Program or HUSKY, LBP**: Connecticut's implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
7. **Medically Necessary or Medical Necessity**: (as defined in Connecticut General Statutes § 17b-259b) Those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain the individual's achievable health and independent functioning provided such services are: (1)

Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community, (B)recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease; (3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers; (4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and (5) based on an assessment of the individual and his or her medical condition.

8. **Prior Authorization**: A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.

**ADDITIONAL RESOURCES AND REFERENCES:**


- Brunner M, Bittorf B, Matzel K. Modern strategies for the treatment of fecal incontinence. Zentralbl Chir. 2019;144(2):190-201.
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- Hong KD, Kim JS, Ji WB, Um JW. Midterm outcomes of injectable bulking agents for fecal incontinence: A systematic review and meta-analysis.
- La Torre F, de la Portilla F. Long-term efficacy of dextranomer in stabilized hyaluronic acid (NASHA/Dx) for treatment of faecal incontinence. Colorectal Dis. 2013;15(5):569-574.
- Leung FW. Treatment of fecal incontinence - review of observational studies (OS) and randomized controlled trials (RCT) related to injection of bulking agent into peri-anal tissue
- Luo C, Samaranayake CB, Plank LD, Bissett IP. Systematic review on the efficacy and safety of injectable bulking agents for passive faecal incontinence. Colorectal Dis. 2010;12(4):296-303.
- Maeda Y, Laurberg S, Norton C. Perianal injectable bulking agents as treatment for faecal incontinence in adults. Cochrane Database Syst Rev. 2010;5:CD007959.
- Maeda Y, Vaizey CJ, Kamm MA. Long-term results of perianal silicone injection for faecal incontinence. Colorectal Dis. 2007;9(4):357-361.
- Malouf AJ, Vaizey CJ, Norton CS, Kamm MA. Internal anal sphincter augmentation for fecal incontinence using injectable silicone biomaterial. Dis Colon Rectum. 2001;44(4):595-600.
- National Institute for Health and Clinical Excellence (NICE). Injectable bulking agents for faecal incontinence. Interventional Procedure Guidance 210. London, UK: NICE; 2007.
- Solesta® (package insert). Edison, NJ: Oceana Therapeutics (US), Inc.; Jan 2014. Accessed November 19, 2014.
- U.S. Food and Drug Administration: FDA News. FDA approves injectable gel to treat fecal incontinence. May 2011. Available at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm257112.htm. Accessed November 19, 2014.

**PUBLICATION HISTORY**

| Status | Date | Action Taken |
|---|---|---|
| Original publication | December 2014 | DSS review. Approved by DSS November 21, 2014 |
| Reviewed | December 2014 | Clinical Quality Sub-committee review. Approved at the December 15, 2014 Clinical Quality Sub-Committee meeting. |
| Updated | August 2015 | Updated definitions for HUSKY A, B, C and D programs at request of DSS. |
| Updated | March 2016 | Updates to language in introductory paragraph pertaining to purpose of policy.<br>Updates to Clinical Guideline section pertaining to definition o Medical Necessity. Updates throughout policy to reflect importance of person-centeredness when reviewing requests for Solesta. Changes approved at the March 2016 Clinical Quality Subcommittee meeting. Changes approved by DSS on April 25, 2016. |
| Updated | March 2017 | Updates to Clinical Guideline section. Update to reference section. Changes approved at the March 8, 2017 Medical Policy Review Committee meeting. Approved by Clinical Quality Subcommittee on March 20, 2017. Approved by DSS on March 27, 2017. |
| Updated | May 2018 | Update to reference section. Change approved at the May 2 2018 Medical Policy Review Committee meeting. Change Approved by the CHNCT Clinical Quality Subcommittee on June 18, 2018. Approved by DSS on June 20, 2018. |
| Updated | April 2019 | Update to Additional Resources and References section. Change approved at the April 24, 2019 CHNCT Medical Reviewer meeting. Change approved by the CHNCT Clinical Quality Subcommittee on June 19, 2019. Approved by DSS on June 21, 2019. |
| Updated | April 2020 | Based on a review of current literature, the policy was update to reflect that use of Solesta® in the treatment of fecal incontinence is investigational and unproven and therefore not medically necessary. References updated.<br><br>Changes approved at the March 11, 2020 CHNCT Medical Reviewer meeting. Approved by the CHNCT Clinical Quality Subcommittee on March 16, 2020. Approved by DSS on April 16, 2020. |
| Updated | March 2021 | Update to Policy section. Further clarified statement that Solesta is considered experimental and investigational by:<br>• Adding “experimental” to statement<br>• Adding “due to insufficient evidence of therapeutic value”<br>Changes approved at the February 10, 2021 CHNCT Medical Reviewer meeting. Approved by the CHNCT Clinical |

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| | | Quality Subcommittee on March 15, 2021. Approved by DSS on March 22, 2021. |
| Reviewed | March 2022 | Reviewed and approved without changes at the March 9, 2022 CHNCT Medical Reviewer meeting. Approved by the CHNCT Clinical Quality Subcommittee on March 21, 2022. Approved by DSS on March 24, 2022. |