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. Treatment with Solesta®may provide an increased level of independence and an ability to participate more fully in self-care while supporting an overall improvement in an individual's health status and quality of life.

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:

- Solesta® may be considered medically necessary for the treatment of fecal incontinence when the:
- Individual is 18 years or older; and
- Has a documented history of fecal incontinence for at least twelve (12) months; and
- The individual has tried and failed conservative therapy e.g., diet, fiber, anti-motility medications (supported by documentation in the medical record); and
- The individual does NOT have any of the following conditions:
    1. Active inflammatory bowel disease;
    2. Immunodeficiency disorders or ongoing immunosuppressive therapy;
    3. Previous radiation treatment to the pelvic area;
    4. Significant mucosal or full thickness rectal prolapse;
    5. Active anorectal conditions including: abscess, fissures, sepsis, bleeding, proctitis, or other infections;
    6. Anorectal atresia, tumors, stenosis or malformation;

7. Rectocele;
8. Rectal varices;
9. Presence of existing implant (other than Solesta®) in the anorectal region;
10. Allergy to hyaluronic acid based products;
11. Grade IV hemorrhoids; or
12. History of anorectal surgery within the previous twelve (12) months.

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:

- American Medical Association, Current Procedural Terminology Manual: 2017
- CGS Medicare: Solesta™ Treatment for Fecal Incontinence. February 9, 2015. Accessed March 6, 2017.
- 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. Updates to Clinical Guideline section pertaining to definition of 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 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.