*Example only. For your convenience, we have highlighted the patient-specific fields on the template below. Please cite all product information in this template appropriately, using the provided references.*

[Physician’s Letterhead]

[Name of Insurance Co] [Date]

[Address of Insurance Co] ]

[City, State, ZIP of Insurer]

**Re: Prior Authorization and Statement of Medical Necessity for Solesta® Injectable Gel Therapy for:**

[Patient Name]

[Name of Policyholder]

[Patient Date of Birth}

[Insurance ID Number of Patient]

Insurance Group Number of Patient]

To Whom It May Concern:

My patient, Patient’s name, is seeking coverage for the use of Solesta® Injectable Gel NASHA/Dx ) to treat her fecal incontinence (FI) (ICD-10 code R15.9).

Patient’s name was diagnosed with fecal incontinence (ICD-10 code R15) on original diagnosis date. Her [Insert any QOL Score available and/or patient-specific details from history] objectively indicates a significant impairment of continence and associated degradation in her quality of life. She has already tried conservative management with dietary changes, oral bulking agents/fiber, constipating medication [Insert medication], and bowel retraining with [Insert biofeedback/pelvic floor therapy], all without success.

She recently has experienced: (add any recent symptoms, condition, treatment affecting the patient’s struggle with Fecal Incontinence. Omit if nothing pertinent). She is suffering and in need of this procedure to prevent additional health issues, social isolation, disruptions in intimate relationships, problems with self-confidence and embarrassment.

Solesta® was approved by the FDA in 2011 for the treatment of fecal incontinence (FI) in patients 18 years and older who have failed conservative therapy11and has been used in over 6,500 patients and studied in ~600 patients.1,2,4,8,10,11 In studies, patients reduced their FI episodes, reduced their symptom burden, and improved all areas of QOL. 80% of patients thru 36 months did not need reintervention after Solesta8,9,10and is proven as a cost-effective therapy for FI.3

There is sufficient medical documentation and evidence to support the current request for Solesta treatment. Additionally, I have provided specifics: (chart notes, dates of conservative treatment failure etc.)

I believe that treatment with Solesta will provide essential clinical benefit in [patient name]'s current course of care, improve her quality of life and may avoid the need to progress to more costly, invasive surgical intervention which can lead to hospitalization, extended time off of work, potential surgical complications, added financial strain and decreased quality of life.

Thank you for an expedient response,

[Physician Signature]

[Physician Name, M.D.]

[Practice Name]

References:

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3. Bernstein MA, Purdy CH, Becker A, Magar R. Three-year cost-effectiveness model for non-animal stabilized hyaluronic acid and dextranomer copolymer compared with sacral nerve stimulation after conservative therapy for the management of fecal incontinence. *Clin Ther*. 2014;36(6). doi:10.1016/j.clinthera.2014.04.010
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9. Quiroz LH, Galliano Jr. DE, Da Silva G, et al. Efficacy and Safety of a Non-Animal Stabilized Hyaluronic Acid/Dextranomer (NASHA/Dx FI [Solesta®]) in Improving Fecal Incontinence: A Prospective, Single-arm, Multicenter, Clinical study with 36 Month Follow-up (Abstract accepted for Presentation). In: PFDWeek 2020.
10. Solesta Post Approval Study (PAS), 2020: 283-patient, 36-month, multi-center PAS with robust long-term outcomes data (recently accepted by FDA, abstract accepted, publication pending
11. U.S. Food & Drug Administration (FDA). Solesta Injectable Gel - Premarket Approval (PMA). https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100014. Accessed April 22, 2020.