*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: Appeal to the denial 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]

Appeal communication letter identification number/ EOB (if any)

To Whom It May Concern:

Please accept this letter as [patient's name] appeal to the decision to deny coverage for the use of Solesta(L8605) Injectable Gel (NASHA/Dx) to treat their fecal incontinence (FI) (ICD-10 code R15.9). It is my understanding based on your letter of denial dated [insert date] that this procedure has been denied because: [quote the specific reason for the denial stated in denial letter].

[patient name] has suffered from Fecal Incontinence (FI) and has failed all conservative therapy and would receive clinical benefits from the use of Solesta®. Solesta® received FDA approval in 2011 for the treatment of FI in patients aged 18 years and older who have not responded to conservative therapy11. It has been utilized in the treatment of over 6,500 patients and extensively studied in approximately 600 patients1,2,4,8,10,11. Clinical studies have consistently demonstrated its effectiveness, with patients experiencing a reduction in FI episodes, a decrease in symptom burden, and an improvement in overall quality of life. Remarkably, up to 80% of patients remained intervention-free for up to 36 months following Solesta treatment8,9,10. Additionally, Solesta has been proven to be a cost-effective therapy for FI3.

L8605 is classified as an Injectable bulking agent, specifically a dextranomer/hyaluronic acid copolymer implant, for use in the anal canal, in a 1 ml formulation.

If you find the attached references insufficient to support our request for policy addition, we kindly request that you provide a detailed rationale for your denial, citing specific reasons. I firmly believe that treatment with Solesta® offers essential clinical benefits for numerous patients and can prevent a decline in their quality of life, as well as the need for further treatments associated with fecal incontinence (FI). Additionally, I have provided: (Patient-specific documentation to combat reason for denial: 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 therapies.

Thank you for an expedient response,

[Physician Signature]

[Physician Name, M.D.]

[Practice Name]

[Practice Address]

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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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.