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[Physician letterhead] [Date]

[Formulary director] [Name of health plan] [Mailing address]

Re: [Patient’s name]

[Plan identification number] [Date of birth]

[Case identification]

Subject: Exception Letter for NATESTO® (testosterone) Nasal Gel, CIII, 5.5 mg/actuation

To whom it may concern:

My name is [physician’s name], and I am a [board-certified medical specialty] [NPI]. I am writing to request a [formulary or tiering] exception for my patient, [patient’s name], who is currently a member of [name of health plan] based on the following reasons\*:

Check applicable box(es) below:

□ Not on formulary

□ Preferred therapy is less effective

□ Tiering change to lower tier

□ Compliance with current product

□ Dexterity challenges

The prescription is for [product, dosage, and frequency], which is medically appropriate and necessary for this patient who has been diagnosed with [condition], [ICD code(s)].

I am requesting that NATESTO® (testosterone) Nasal Gel be made available to my patient.

In the past, [patient’s name] has attempted other treatments for [condition], but those trials have failed due to either [inadequate efficacy], [lack of tolerability], or [administration challenges].

|  |  |  |
| --- | --- | --- |
| **Past Treatment(s)†** | **Start/Stop Dates** | **Reason(s) for Discontinuing** |
| [Drug name] | [MM/YY] - [MM/YY] | [Please list side effects, lack of efficacy, etc] |
| [Drug name] | [MM/YY] - [MM/YY] | [Please list side effects, lack of efficacy, etc] |

The patient’s present treatment(s) are as follows:

|  |  |  |
| --- | --- | --- |
| **Current Treatment(s)†** | **Start Date** | **Dosage** |
| [Drug name] | [MM/YY] | [XX] |
| [Drug name] | [MM/YY] | [XX] |

Currently, [patient’s name] has the following unresolved symptoms:

• [Symptom 1]

• [Symptom 2]

[For Fertility Maintenance Naïve to TTh: In addition, this patient has expressed a desire to try to maintain his fertility. His current total sperm count and total motile sperm count are [count 3, count 4], documented on [date]. Due to the short-acting nature of Natesto and the decreased effect on spermatogenesis suppression reported‡ with Natesto, I have further reason to believe that Natesto is an appropriate treatment for my patient.]

[For Fertility Maintenance Prior TTh: In addition, this patient has expressed a desire to try to [maintain/regain] his fertility. Before starting testosterone therapy with [prior testosterone therapy] on [date], his total sperm count and total motile sperm count were [count 1, count 2], documented on [date], and his current total sperm count and total motile sperm count are [count 3, count 4], documented on [date]. Due to the short-acting nature of Natesto and the decreased effect on spermatogenesis suppression reported‡ with Natesto, I have further reason to believe that Natesto is an appropriate treatment for my patient.]

[For Polycythemia Naïve to TTh: In addition, this patient [has been diagnosed with/is at risk of developing] [polycythemia/erythrocytosis] and presents with a clinical history of [elevated HCT/sleep apnea/past or current smoker/COPD/obesity]. Clinical studies have shown that the risk of developing polycythemia in patients using Natesto is low.]

[For Polycythemia Prior TTh: In addition, this patient [has been diagnosed with/is at risk of developing] [polycythemia/erythrocytosis] and presents with a clinical history of [elevated HCT/sleep apnea/past or current smoker/COPD/obesity]. Clinical studies have shown that the risk of developing polycythemia in patients using Natesto is low.]

Along with this letter, I have enclosed a copy of my patient’s medical records and a Letter of Medical Necessity. The letter describes why Natesto is medically necessary for my patient’s care.

[Explain why other formulations are not effective.]

To summarize, I consider Natesto to be the best option in successfully treating my patient’s [condition].

Please contact me, [physician’s name], at [phone #] to answer any pending questions. Sincerely,

[Physician’s signature]

[Physician’s name]

[Physician’s medical specialty] [Physician’s National Provider Number (NPI)] [Physician’s practice name]

[Phone #] [Fax #]

Encl: [Medical records, photo(s), Letter of Medical Necessity, case number, written response to denial]

\*Include patient’s medical records and supporting documentation, including clinical evaluation.

†Identify drug name, strength, dosage form, and therapeutic outcome.

‡Primary outcome from a phase 4, single-site, open-label, single-arm clinical trial (N=60).1

**Reference: 1.** Data on file. Acerus Pharmaceuticals Corporation.

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