**Patient Letter of Medical Necessity for MYCAPSSA® (octreotide): Considerations and Sample Template**

Dear Provider,

You can consider asking patients to prepare a letter of medical necessity to the insurer to support an appeal for MYCAPSSA treatment. A patient narrative can accompany your appeal. You can give the patient the template provided on page 3 to complete or use the list of topic suggestions below to help the patient get started.

## Suggestions for Patients to Write Their Own MYCAPSSA Appeal Letter

Here are some examples of questions you can think about to help describe the impact of acromegaly on your life and why an oral treatment would be more convenient. You can include other issues that are important to you:

- At what age were you diagnosed with acromegaly?
- How has acromegaly impacted your quality of life?
- Has treatment with injected octreotide or lanreotide helped you?
- Have you had any side effects with injected octreotide or lanreotide treatment?
- Why would you prefer an oral medication?
- If you are writing to support a request for lower copay or coinsurance, describe why the current cost is a financial burden

Include the following information of your appeal letter:

- The name of your insurance plan
- Your group and member number for your insurance plan
- Your address and phone number(s)

## Indication and Important Safety Information

### Indication

MYCAPSSA (octreotide) delayed-release capsules, for oral use, is a somatostatin analog indicated for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide.

### Important Safety Information

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### CONTRAINDICATIONS

Hypersensitivity to octreotide or any of the components of MYCAPSSA. Anaphylactoid reactions, including anaphylactic shock, have been reported in patients receiving octreotide.

### WARNINGS AND PRECAUTIONS

MYCAPSSA can cause problems with the gallbladder. Monitor patients periodically. Discontinue if complications of cholelithiasis are suspected.
Blood sugar, thyroid levels, and vitamin $B_{12}$ levels should be monitored and treated accordingly.

Bradycardia, arrhythmia, or conduction abnormalities may occur. Treatment with drugs that have bradycardia effects may need to be adjusted.

**Important Safety Information (Continued)**

**ADVERSE REACTIONS**
The most common adverse reactions (incidence >10%) are nausea, diarrhea, headache, arthralgia, asthenia, hyperhidrosis, peripheral swelling, blood glucose increased, vomiting, abdominal discomfort, dyspepsia, sinusitis, and osteoarthritis.

**DRUG INTERACTIONS**
The following drugs require monitoring and possible dose adjustment when used with MYCAPSSA: cyclosporine, insulin, antidiabetic drugs, calcium channel blockers, beta blockers, lisinopril, digoxin, bromocriptine, and drugs mainly metabolized by CYP3A4. Counsel women taking an oral contraceptive to use an alternative non-hormonal method of contraception or a back-up method when taking MYCAPSSA.

Patients taking proton pump inhibitors, H2-receptor antagonists, or antacids concomitantly with MYCAPSSA may require increased dosages of MYCAPSSA.

**PREGNANCY**
Advise premenopausal females of the potential for an unintended pregnancy.

**Please contact Chiesi Farmaceutici S.p.A. at 1-888-661-9260 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

**Please see full Prescribing Information, including Medication Guide.**

**Patient Letter of Medical Necessity for MYCAPSSA® (octreotide)**

**Template**

[Date]
[Patient name]
[Patient Address]
[Patient Phone Number(s)]
[Patient Date of Birth]

[Insurance Plan Name]
[Insurance Group Number]
[Insurance Member Number]
[Prescribing Provider Name]

To whom it may concern:

My doctor, [enter name of doctor], recommended Mycapssa® (octreotide) for the treatment of acromegaly. I have had acromegaly since I was [enter age at diagnosis] years old. I have been under the care of [enter name of doctor] since [enter date you started seeing current doctor].

I have tried other treatments to control my acromegaly, which include [name treatments]. On [named treatment], I experienced [factual statement of patient's reactions and experience]. [Repeated for additional treatments tried.] Due to my experience on other treatments, my doctor and I agree that switching to Mycapssa makes sense.

[If you are writing to request a lower copay, describe why the current copay amount is financial burden.]

I would be very grateful if you would cover oral Mycapssa as requested by my doctor. My doctor can be reached at [insert doctor's phone number].

Sincerely,

[Print your name]

[Sign your name]

[Insert your address]

[Insert your phone number]

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