Mycapssa® (octreotide) capsules 20mg

Prior Authorization (PA) Checklist

Your patient's health plan may require a PA to approve use of MYCAPSSA® (octreotide). Complete and accurate PA requests may expedite approval for patient treatment.

The checklist below can help you organize recommended information and documentation that your patient's health plan may require for a PA for MYCAPSSA. Be sure to check with your patient's health plan to confirm the specific process.

Recommended supporting clinical documentation for PA requests:

- ☐ Letter of Medical Necessity highlighting clinical rationale for treatment with MYCAPSSA
- ☐ Documentation of acromegaly diagnosis (ICD-10 Code: E22.0: Acromegaly and Pituitary Gigantism and/or D35.2 Benign Neoplasm of Pituitary Gland)
- ☐ Requested dose of MYCAPSSA
- ☐ Patient, at any time, has received, responded to and tolerated injectable octreotide or lanreotide (include dates)
- ☐ Any plan-specific PA forms
- ☐ Clinic visit notes
- ☐ IGF-I lab values
- ☐ FDA approval letter, package insert, and peer-reviewed scientific literature to support use of MYCAPSSA

If applicable to your patient:

- ☐ Documentation of experience with current and prior therapies, including response and/or challenges

Additional considerations:

If a PA is denied, the physician can appeal the decision on the patient's behalf by reviewing the denial letter, correcting or submitting any outstanding information, and/or writing a letter of appeal

If a patient does not meet the PA requirements or if MYCAPSSA is not on the health plan's formulary, a formulary exception can be requested based on medical necessity

Quantity limits are sometimes put in place by health plans to manage the amount of a specific product a patient can receive within a defined period. If a patient has a medically necessary reason for exceeding the quantity limits put in place by their health plan, a formulary exception may also be requested

Available resources:

The following resources are available to help with PA submissions for MYCAPSSA:

- Sample Letter of Medical Necessity
- Sample Letter of Appeal

For additional support, please call Chiesi Total Care at (1-833-346-2277) 7:00 AM – 7:00 PM (Central Time)

Chiesi TOTAL care℠

Please see accompanying full Prescribing Information for MYCAPSSA.

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(octreotide) capsules 20mg

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE

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.

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 B12 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.

New onset of steatorrhea, stool discoloration, loose stools, abdominal bloating, and weight loss may occur with MYCAPSSA and other somatostatin analogs. If new occurrence or worsening of these symptoms are reported, evaluate for potential pancreatic exocrine insufficiency and manage accordingly.

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 to use an alternative non-hormonal method of contraception or a back-up method when MYCAPSSA is used with combined oral contraceptives.

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.

To report SUSPECTED ADVERSE REACTIONS, contact the product information department at 1-844-312-2462 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see accompanying full Prescribing Information for MYCAPSSA.

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