



Mycapssa[®]
(octreotide) capsules
20mg

Starter Kit

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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

 **Chiesi**
TOTAL
*care*SM

Consistent control for patients with acromegaly with daily oral MYCAPSSA[®]

What's inside



Getting a Patient Started on MYCAPSSA

- Rx form
- Patient consent form



MYCAPSSA Prior Authorization and Access Guide

- Medical necessity letter template
- Appeal letter template



MYCAPSSA Dosing and Administration Guide



Copay Support Information

Please refer to the full Terms and Conditions in the back pocket for additional eligibility requirements.



US Prescribing Information



Contact Information Card



Mycapssa[®]
(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.

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.

To report SUSPECTED ADVERSE REACTIONS, please contact Chiesi Farmaceutici S.p.A. at 1-888-661-9260 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

For more information, visit mycapssa.com.

Chiesi Total CareSM Program offered through AcariaHealth Specialty Pharmacy.

© 2024 CHIESI USA.

MYCAPSSA[®] is a registered trademark owned by the Chiesi Group.

Chiesi Total CareSM is a service mark of CHIESI FARMACEUTICI S.p.A.

Becky,
MYCAPSSA
patient



Getting Started Guide

To get a patient started on MYCAPSSA®
follow 2 steps outlined in this guide

Visit chiesitotalcare.com
or call 1-833-346-2277
We're ready to help!

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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.


 **TOTAL**
*care*SM

Step 1: Fill out the Prescription and Patient Consent Forms



Prescription Form

To Be Completed by Prescriber



1. First prescription for the patient: Fax completed form to 1-833-746-2277
2. Subsequent prescription: May be e-script via AcariaHealth Specialty Pharmacy in your EMR/HMR system Call 1-833-346-2277 if you have questions regarding this form or contact Chiesi Total Care™

1. PATIENT INFORMATION (all fields in this section are mandatory)

Patient Name (First, Middle, Last) _____ Email _____
 Last 4 of Social Security # _____ Gender at birth Male Female Date of Birth _____ (mm/dd/yyyy)
 Address _____ City _____ State _____ Zip _____
 Mobile # _____ Alternative Phone # _____ Language: English Other _____
 Caregiver Name _____ OK to leave message
 Email _____ Caregiver Phone # _____
 Allergies _____ Current Medications: _____
 No known drug allergies (NKDA)

2: INSURANCE INFORMATION (check the relevant box and complete as much as possible)

Please attach copies of both sides of the patient's insurance card.

Medicare Medicaid Commercial/Private Other Uninsured

Primary Insurance Payer _____ Plan Name _____
 Phone # _____ Policy ID # _____
 Group # _____ BIN _____
 PCN _____ Policy Holder's Name: _____
 Policy Holder's Date of Birth _____ Policy Holder's Relationship to Patient _____

3: PRESCRIBER INFORMATION* (all fields in this section are mandatory)

The prescriber is to comply with his/her state specific prescription requirements such as e-prescribing, state specific prescription form fax language, etc. Non-compliance with state specific requirements could result in outreach to the prescriber.

Name (First, Middle, Last) _____ Prescriber NPI # _____
 Prescriber Tax ID #: _____ Facility Name _____
 Facility Address _____ City _____ State _____ Zip _____
 Facility Phone # _____ Preferred Fax # _____
 Primary Contact Name _____ Title/Role _____
 Primary Contact Phone # _____ Primary Contact Email _____

4: TREATMENT AND PRESCRIBING INFORMATION (mandatory)

Rx Treatment: MYCAPSSA® (octreotide) delayed-release oral capsules NDC: 69880-120-28. Dispense as written.
 Please check a box below for medication strength* (mandatory)

	Recommended to check additional strengths for titration needs		
<p>Patient, at any time, has been prescribed octreotide or lanreotide</p> <p><input type="checkbox"/> yes <input type="checkbox"/> no</p>	<p><input type="checkbox"/> ICD-10/Diagnosis: E22.0 (acromegaly and pituitary gigantism)</p> <p><input type="checkbox"/> ICD-10/Diagnosis: D35.2 (benign neoplasm of the pituitary gland)</p> <p><input type="checkbox"/> ICD-10/Diagnosis: F40.231 (needle phobia)</p> <p><input type="checkbox"/> Other ICD-10/Diagnosis: _____</p>	<p><input type="checkbox"/> MYCAPSSA 40 mg Starting Dose</p> <p>Dispense: MYCAPSSA 20 mg capsules Sig: Take 1 capsule PO BID</p> <p><input type="checkbox"/> QTY: 56 <input type="checkbox"/> QTY: 168</p> <p>Number of Refills _____</p>	<p><input type="checkbox"/> MYCAPSSA 60 mg</p> <p>Dispense: MYCAPSSA 20 mg capsules Sig: Take 2 capsule PO QAM and 1 capsule PO QPM</p> <p><input type="checkbox"/> QTY: 84 <input type="checkbox"/> QTY: 252</p> <p>Number of Refills _____</p>
		<p><input type="checkbox"/> MYCAPSSA 80 mg</p> <p>Dispense: MYCAPSSA 20 mg capsules Sig: Take 2 capsule PO BID</p> <p><input type="checkbox"/> QTY: 112 <input type="checkbox"/> QTY: 336</p> <p>Number of Refills _____</p>	


PRESCRIBER AUTHORIZATION* (mandatory)

By signing below, I certify that I am part of the Chiesi Total Care Program, that the therapy described above is medically necessary, and that the information provided is accurate to the best of my knowledge. I also attest that I have obtained the patient's authorization to release the above information and such other personal information as may be necessary to the Chiesi Total Care Program and/or their agents. If the patient is 18 years old or younger, I attest that I have obtained permission from the patient's legal guardian.

Licensed Prescriber Signature (required—no stamps) _____
 Printed Name _____ Date _____

ATTENTION: E-prescribe or use the official state prescription form where required by state law.
No stamped signatures or signing on behalf of the prescriber.

Scan for digital RX form.



Product: MYCAPSSA®

Phone: 1-833-346-2277

JSA, Inc. ("Chiesi") product. Program support may include: and reviewing eligibility for financial assistance and copy and (4) providing disease-, medication-, and adherence-

(MM/DD/YY): _____

RE

Chiesi USA, Inc., and its affiliates, service providers, agents, providers, and their staff, my health plan, patient assistance about my diagnosis, treatment, and lab results), personal as prescriptions and plans) (together my "Information") in conduct other business activities, and complete government lives (together, "Chiesi") including providers of alternate Program") for Healthcare Providers and patients for the mail, phone, email, and text message*), tailor Program-pense Chiesi products to me. Chiesi may also de-identify business purposes. I understand that once my Information ever, Chiesi will only process and disclose my Information w.chiesiusa.com/privacy-policy/.

Chiesi Care Program, you understand that Chiesi USA, Inc. may s://www.chiesiusa.com/privacy-policy/. To opt-out of the use 187. Only you, or someone legally authorized to act on your s defined in the California Consumer Privacy Act ("CCPA").

may affect my treatment, insurance coverage, or eligibility for

letter requesting cancellation to Chiesi Total Care, 8517 nd personal data rights, Chiesi will no longer process my d on this Authorization prior to receipt of the cancellation. quired by state or local law.

to Chiesi. I acknowledge that if I am eligible for infusion knowledge that if I am enrolled in a government-funded stand and agree that if my insurance information changes sible, and any such change may affect my eligibility for

Chiesi Total Care support programs on page 2 of this document.

Chiesi about opportunities for you to provide feedback to us

vide feedback.

consent to receiving text messages is not a condition of ext messages by replying STOP to any text from Chiesi

ges.

ate (MM/DD/YY): _____

to Patient: _____

and I agree that Chiesi Total Care will not pay those fees.

Office Contact Person: _____ Office Phone: _____

A

B

IMPORTANT SAFETY INFORMATION

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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

Specify appropriate ICD-10 Diagnosis code(s) for secondary diagnosis

(Other uses are at prescriber's discretion)

ICD-10 Diagnosis Codes

A

Diagnosis	Current indication
E22.0	Acromegaly and pituitary gigantism
D35.2	Benign neoplasm of the pituitary gland
F40.231	Needle phobia

Intended as a reference for coding and billing for product and associated services. Not intended to be a directive, nor does the use of the recommended codes guarantee reimbursement. Providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

Specify formulation and dosing schedule

B

Start

Manage patients' expectations when starting MYCAPSSA

- Start patients on the 20 mg BID oral dose
- Ensure they take MYCAPSSA with a glass of water
- Coach them on finding a routine for taking MYCAPSSA on an empty stomach, either 1 hour before or 2 hours after eating

Titrate

- Titrate based on IGF-1 levels and patients signs and symptoms.
- Titrate in 20 mg increments from 40 mg up to a maximum daily dosage of 80 mg.
- Recommended to select additional strengths for titration needs.

Step 2: Once you have completed the form:

1. **Attach copies of patient insurance and prescription cards – front and back.**
2. **First prescription for the patient:**

THE FIRST COPY OF THE FORM MUST BE FAXED FOR EACH PATIENT. Fax completed form to Chiesi Total CareSM at **1-833-746-2277. PLEASE COMPLETE ONE FORM PER PATIENT.**

3. **Subsequent prescriptions:**

If you wish to send additional forms via e-script please search for "AcariaHealth" in your EMR/HMR's e-prescribing software.

The fillable pdf can be downloaded and saved for future use.

Scan the QR code to download a copy.





If you have questions, visit chiesitotalcare.com
or call 1-833-346-2277 – we're ready to help!

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.

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.

To report SUSPECTED ADVERSE REACTIONS, please contact Chiesi Farmaceutici S.p.A. at 1-888-661-9260 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

References: 1. Mycapssa® (octreotide) Prescribing Information. Amryt, March 2022.

For more information, visit mycapssa.com.

Chiesi Total CareSM Program offered through AcariaHealth Specialty Pharmacy.

© 2024 CHIESI USA.

MYCAPSSA® is a registered trademark owned by the Chiesi Group.

Chiesi Total CareSM is a service mark of CHIESI FARMACEUTICI S.p.A.

PP-MC-0002 V1.0 2024



Bonnie,
MYCAPSSA
patient



Dosing and Administration Guide

Visit chiesitotalcare.com
or call 1-833-346-2277
We're ready to help!

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

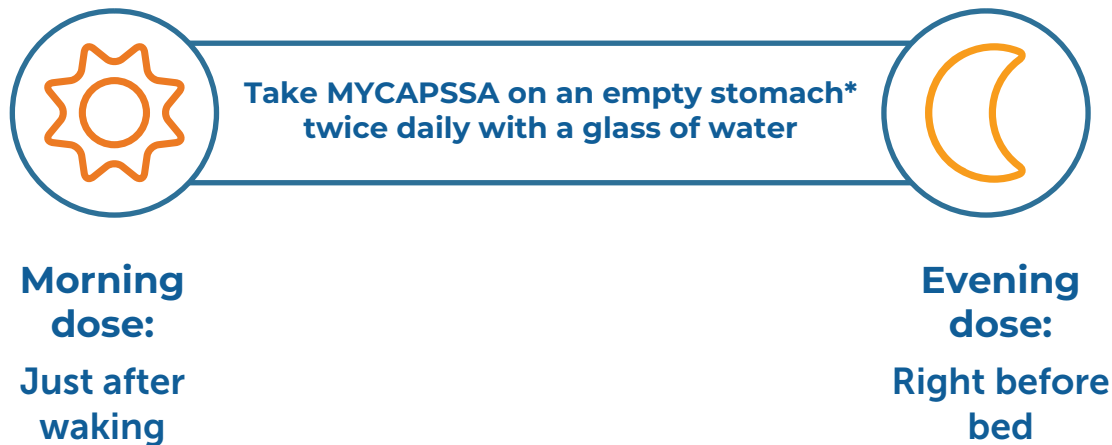
Hypersensitivity to octreotide or any of the components of MYCAPSSA. Anaphylactoid reactions, including anaphylactic shock, have been reported in patients receiving octreotide.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.



Getting Patients Started on Daily Oral MYCAPSSA is Straightforward

Example dosing schedule:



Each wallet of MYCAPSSA comes with 28 capsules. Each MYCAPSSA capsule is 20 mg.



* One hour before or two hours after a meal

IMPORTANT SAFETY INFORMATION

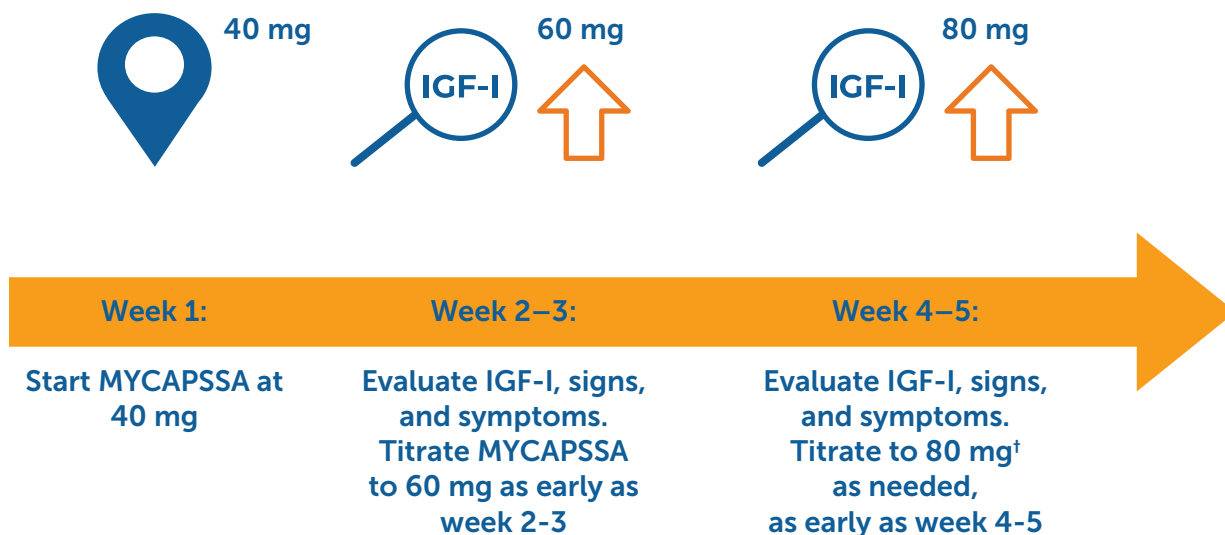
ADVERSE REACTIONS

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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

Starting and Optimizing MYCAPSSA

Example titration schedule:*



Once the maintenance dosage of MYCAPSSA is achieved, monitor IGF-I levels and acromegaly signs and symptoms monthly.

*The example titration schedule above reflects the total daily dose of MYCAPSSA. Refer to the full Prescribing Information for a detailed dosing schedule.

[†]The maximum daily dose of MYCAPSSA is 80 mg.



If you have questions, visit chiesitotalcare.com
or call 1-833-346-2277 – we're ready to help!

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.

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.

To report SUSPECTED ADVERSE REACTIONS, please contact Chiesi Farmaceutici S.p.A. at 1-888-661-9260 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

For more information, visit mycapssa.com.

Chiesi Total CareSM Program offered through AcariaHealth Specialty Pharmacy.

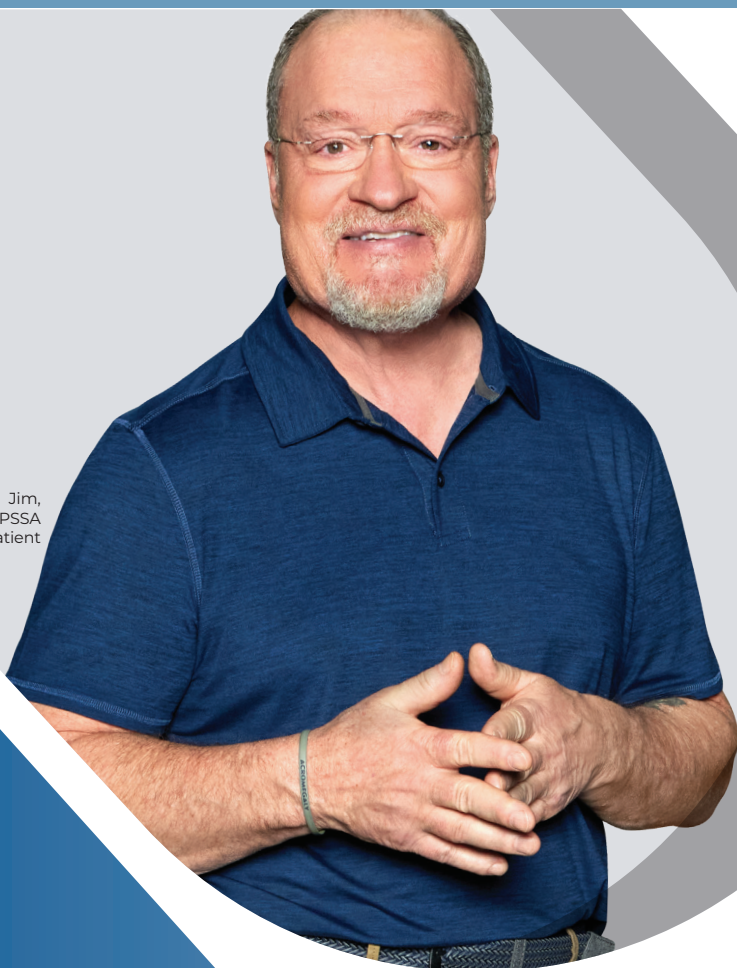
© 2024 CHIESI USA.

MYCAPSSA[®] is a registered trademark owned by the Chiesi Group.
Chiesi Total CareSM is a service mark of CHIESI FARMACEUTICI S.p.A.

PP-MC-0004 V1.0 2024



Jim,
MYCAPSSA
patient



Prior Authorization and Access Guide

Visit chiesitotalcare.com
or call 1-833-346-2277
We're ready to help!

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

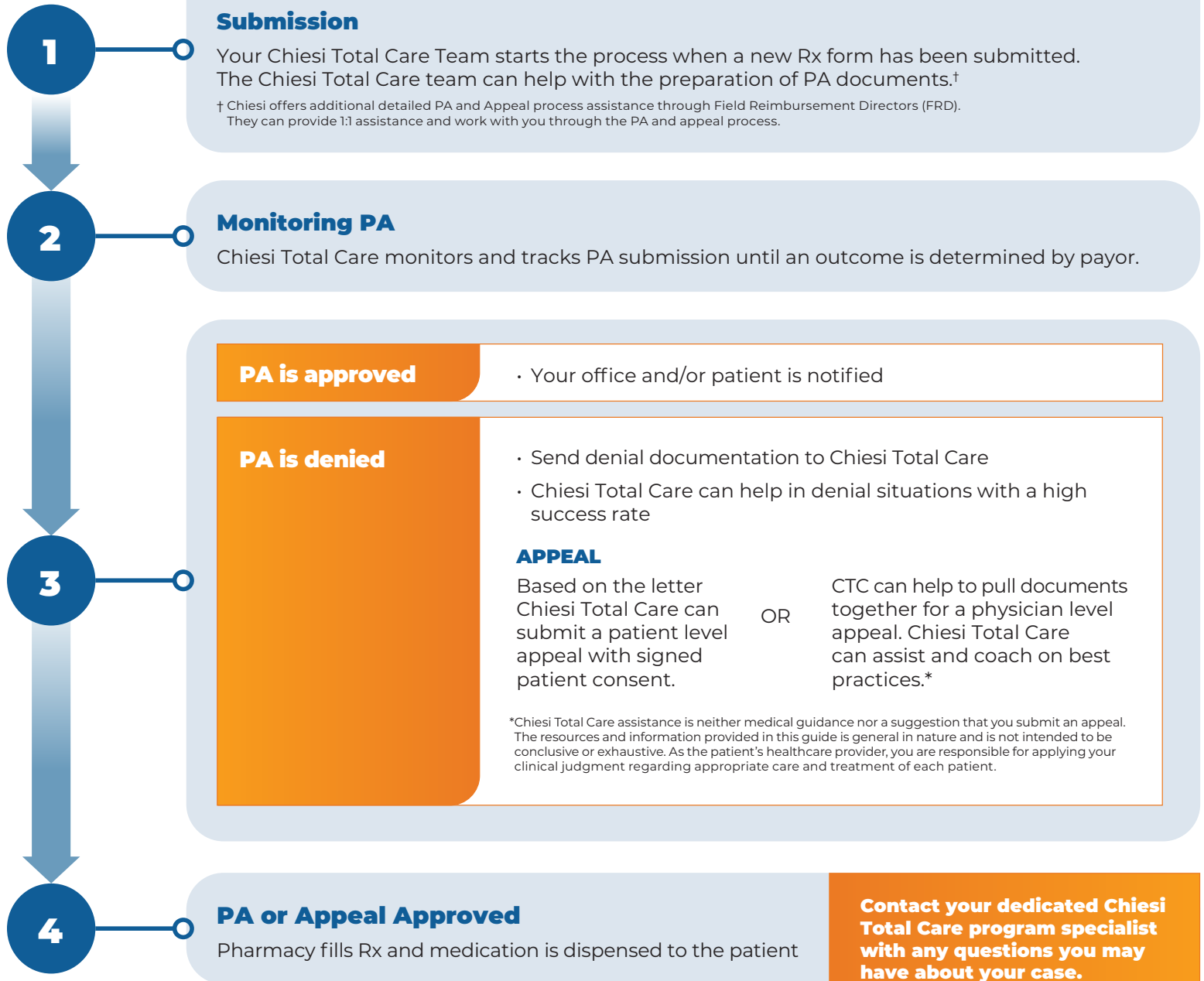
Hypersensitivity to octreotide or any of the components of MYCAPSSA. Anaphylactoid reactions, including anaphylactic shock, have been reported in patients receiving octreotide.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.



Chiesi Total CareSM (CTC) will submit for insurance reimbursement and help you navigate prior authorization (PA).

Here's a step-by-step look at the process



Contact your dedicated Chiesi Total Care program specialist with any questions you may have about your case.

Chiesi also offers patient education liaison (PEL) services for enrolled patients to further support your patients on MYCAPSSA.

PA denied? Chiesi Total Care is here to help.

It's not uncommon for the first PA submission to be denied. With a long track record of success in gaining PA and appeal approvals, Chiesi Total Care is here to provide assistance with the appeal process. Chiesi Total Care will assist in providing additional resources and/or publications depending on the reasons for denial. To request a copy of an additional resource or publication, please reach out directly to us.medical@chiesi.com.

Visit chiesitotalcare.com or call 1-833-346-2277



We provide updates on your patient's therapy and alert the office should there be any concerns. We also support patients by helping them cope with side effects and answering questions.

We can help by:

- Alerting when to refill or when refills are being missed
- Counseling patients on managing side effects
- Providing 24/7 pharmacist access
- Enrolling patients in the MYCAPSSA Copay Program – patients may pay as little as \$0 if eligible[‡]



[‡] Please refer to the full Terms and Conditions in the back pocket for additional eligibility requirements.

Lesa, Chiesi Total Care pharmacist

Here is a checklist of best practices for Prior Authorization submission:

- Include pertinent clinical notes, dates, and laboratory findings
- Include medical rationale for why the patient cannot use preferred formulary drugs
- Include prescribing practitioner NPI number and contact information
- Include therapeutic alternatives that were tried in the past

Important Safety Information

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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.



If you have questions, visit chiesitotalcare.com
or call 1-833-346-2277 – we're ready to help!

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.

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.

To report SUSPECTED ADVERSE REACTIONS, please contact Chiesi Farmaceutici S.p.A. at 1-888-661-9260 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

For more information, visit mycapssa.com.

Chiesi Total CareSM Program offered through AcariaHealth Specialty Pharmacy.

© 2024 CHIESI USA.

MYCAPSSA[®] is a registered trademark owned by the Chiesi Group.

Chiesi Total CareSM is a service mark of CHIESI FARMACEUTICI S.p.A.

PP-MC-0003 V1.0 2024





**SCAN THE QR CODE
FOR THE DIGITAL RX FORM**



BY PHONE

1-833-346-2277



BY FAX

1-833-746-2277



HOURS OF OPERATION

Monday to Friday 7:00am – 7:00pm
(Central Time)

For more information, visit chiesitotalcare.com

Chiesi Total Care Program offered through AcariaHealth Specialty Pharmacy.

©Chiesi USA, Inc. 2024. All rights reserved. Chiesi Total CareSM is a service mark of CHIESI FARMACEUTICI S.p.A.

PP-MC-0005 V2.0 2024

Sample Letter of Appeal

Please Note: By downloading materials from this link, you agree to all the following. These materials are available for download and public personal use. These materials have no value and are not to be re-sold or repurposed. They are solely for your personal use. No purchase from or relationship with Chiesi Total CareSM is required to download or use these materials. Chiesi Total CareSM makes no representations or warranties about these materials or their fitness for any specific use. Chiesi Total CareSM is not responsible for any changes made to these template documents. All billing and coding decisions are the responsibility of the relevant physician. Chiesi Total CareSM does not guarantee any specific reimbursement or favorable results.

Using this template:

- Fill in the template using the instructions highlighted in blue.
- Once you have filled in the information, remove any remaining instructions in blue.
- Select all the text and change the font to black so the whole document appears as one letter.

Use the list above as a checklist to make sure you have completed these steps prior to sending. **It is important to follow these steps to ensure the letter is clear and concise.**

[Insurance Company]
[Address]
[City, State, Zip]

Re: [Patient Name]
[Policy #]
[DOB]
[Address]
[City, State, Zip]

To Whom It May Concern:

I am writing to appeal the denial of benefits for the use of [Product name (generic name)] for services requested for [Patient Name, ID#, Group #]. Included in this letter of appeal are information on the treatment rationale, medical records, medical necessity data and medical studies confirming currently prescribed product as an effective treatment for the diagnosis associated with [ICD10 Code].

Treatment Rationale:

[Provide information on patient response and history to past treatments and anticipated prognosis and rationale for the currently prescribed product].

Outline of Medical Studies:

[Outline a brief overview of the studies evaluating the use of the currently prescribed product in this condition and/or patient population. Remember to include the FDA approved indications and usage].

Medical Record Information:

[Highlight key dates and entries of the medical record how the currently prescribed product is used].

Per the included medical information, it is my professional opinion that the currently prescribed product is medically necessary in treating the patient and the denials for the patient's use of the drug should be reversed. Please call my office at [Office Phone Number] if I can provide further information or speak with a review board to appeal the denial of coverage decision. I look forward to reaching resolution of overturning the denied status of the currently prescribed product for this patient.

Sincerely,

[Physician Name and Signature]

[Phone Number]

Enclosure: [Original denial notification copy]

Sample Letter of Medical Necessity

Please Note: By downloading materials from this website, you agree to all the following. These materials are available for download and public personal use. These materials have no value and are not to be re-sold or repurposed. They are solely for your personal use. No purchase from or relationship with Chiesi Total CareSM is required to download or use these materials. Chiesi Total CareSM makes no representations or warranties about these materials or their fitness for any specific use. Chiesi Total CareSM is not responsible for any changes made to these template documents. All billing and coding decisions are the responsibility of the relevant physician. Chiesi Total CareSM does not guarantee any specific reimbursement or favorable results.

Using this template:

- Fill in the template using the instructions highlighted in blue.
- Once you have filled in the information, remove any remaining instructions in blue.
- Select all the text and change the font to black so the whole document appears as one letter.

Use the steps above as a checklist to make sure you have completed these steps prior to sending. **It is important to follow these steps to ensure the letter is clear and concise.**

[Insurance Company]
[Address]
[City, State, Zip]

Re: [Patient Name]
[Policy #]
[DOB]
[Address]
[City, State, Zip]

To Whom It May Concern:

I am writing this letter of medical necessity on behalf of [Patient Name, ID#, Group #] to request coverage for [Product name (generic name)]. Included in this letter of medical necessity is information on the treatment rationale, medical records, medical necessity data and medical studies confirming currently prescribed product as an effective treatment for the diagnosis associated with [ICD10 Code].

Treatment Rationale:

[Provide information on patient response and history to past treatments and anticipated prognosis and rationale for the currently prescribed product].

Outline of Medical Studies:

[Outline a brief overview of the studies evaluating the use of the currently prescribed product in this condition and/or patient population. Remember to include the FDA approved indications and usage].

Medical Record Information:

[Highlight key dates and entries of the medical record how the currently prescribed product is used].

Per the included medical information, it is my professional opinion that the currently prescribed product is medically necessary in treating the patient and the denials for the patient's use of the drug should be reversed. Please call my office at [Office Phone Number] if I can provide further information.

Sincerely,

[Physician Name and Signature]

[Phone Number]

Enclosure: [As required]

1. First prescription for the patient: Fax completed form to 1-833-746-2277
2. Subsequent prescription: May be e-script via AcariaHealth Specialty Pharmacy in your EMR/HMR system Call 1-833-346-2277
if you have questions regarding this form or contact Chiesi Total CareSM

1. PATIENT INFORMATION (all fields in this section are mandatory)

Patient Name (First, Middle, Last) _____ Email _____
 Last 4 of Social Security # _____ Gender at birth Male Female Date of Birth _____ (mm/dd/yyyy)
 Address _____ City _____ State _____ Zip _____
 Mobile # _____ Alternative Phone # _____ Language: English Other _____
 Caregiver Name _____ OK to leave message
 Email _____ Caregiver Phone # _____
 Allergies _____ Current Medications: _____
 No known drug allergies (NKDA)

2: INSURANCE INFORMATION (check the relevant box and complete as much as possible)

Please attach copies of both sides of the patient's insurance card.

Medicare Medicaid Commercial/Private Other Uninsured
 Primary Insurance Payer _____ Plan Name _____
 Phone # _____ Policy ID # _____
 Group # _____ BIN _____
 PCN _____ Policy Holder's Name: _____
 Policy Holder's Date of Birth _____ Policy Holder's Relationship to Patient _____

3: PRESCRIBER INFORMATION* (all fields in this section are mandatory)

The prescriber is to comply with his/her state specific prescription requirements such as e-prescribing, state specific prescription form fax language, etc. Non-compliance with state specific requirements could result in outreach to the prescriber.

Name (First, Middle, Last) _____ Prescriber NPI # _____
 Prescriber Tax ID #: _____ Facility Name _____
 Facility Address _____ City _____ State _____ Zip _____
 Facility Phone # _____ Preferred Fax # _____
 Primary Contact Name _____ Title/Role _____
 Primary Contact Phone # _____ Primary Contact Email _____

4: TREATMENT AND PRESCRIBING INFORMATION (mandatory)

Rx Treatment: MYCAPSSA[®] (octreotide) delayed-release oral capsules NDC: 69880-120-28. Dispense as written.
Please check a box below for medication strength* (mandatory)

Recommended to check additional strengths for titration needs

Patient, at any time, has been prescribed octreotide or lanreotide

yes
 no

ICD-10/Diagnosis: E22.0 (acromegaly and pituitary gigantism)

ICD-10/Diagnosis: D35.2 (benign neoplasm of the pituitary gland)

ICD-10/Diagnosis: F40.231 (needle phobia)

Other ICD-10/Diagnosis: _____

MYCAPSSA 40 mg
Starting Dose

Dispense: MYCAPSSA 20 mg capsules Sig: Take 1 capsule PO BID

QTY: 56
 QTY: 168

Number of Refills _____

MYCAPSSA 60 mg

Dispense: MYCAPSSA 20 mg capsules Sig: Take 2 capsule PO QAM and 1 capsule PO QPM

QTY: 84
 QTY: 252

Number of Refills _____

MYCAPSSA 80 mg

Dispense: MYCAPSSA 20 mg capsules Sig: Take 2 capsule PO BID

QTY: 112
 QTY: 336

Number of Refills _____

PRESCRIBER AUTHORIZATION* (mandatory)

By signing below, I certify that I am part of the Chiesi Total Care Program, that the therapy described above is medically necessary, and that the information provided is accurate to the best of my knowledge. I also attest that I have obtained the patient's authorization to release the above information and such other personal information as may be necessary to the Chiesi Total Care Program and/or their agents. If the patient is 18 years old or younger, I attest that I have obtained permission from the patient's legal guardian.

Licensed Prescriber Signature (required—no stamps) _____

Printed Name _____ Date _____



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.

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.

To report SUSPECTED ADVERSE REACTIONS, please contact Chiesi Farmaceutici S.p.A. at 1-888-661-9260 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Chiesi Total Care Program offered through AcariaHealth Specialty Pharmacy.

CHIESI TOTAL CARE



PHONE
1-833-346-2277



HOURS OF OPERATION
Monday to Friday
7:00am - 7:00pm (Central Time)



FAX
1-833-746-2277



WEBSITE
chiesitotalcare.com

For more information, visit mycapssa.com.

© 2024 CHIESI USA.

MYCAPSSA® is a registered trademark owned by the Chiesi Group.

Chiesi Total CareSM is a service mark of CHIESI FARMACEUTICI S.p.A.

PP-MC-0028 V1.0



Mycapssa[®]
(octreotide) capsules
20mg



Patient Consent Form

Product: MYCAPSSA®

Fax completed form to Chiesi Total CareSM at 1-833-746-2277 | Phone: 1-833-346-2277

Chiesi Total Care (the "Program") provides product support to eligible patients who have been prescribed a Chiesi USA, Inc. ("Chiesi") product. Program support may include: (1) reimbursement and financial support (such as investigating insurance coverage, confirming out-of-pocket costs, and reviewing eligibility for financial assistance and copay programs); (2) working with patients and pharmacies to fill prescriptions; (3) home infusion support (if applicable); and (4) providing disease-, medication-, and adherence-related educational resources and communications, including access to a Chiesi Patient Education Liaison.

Patient Name: _____ Date of Birth (MM/DD/YY): _____

ENROLLMENT INTO CHIESI TOTAL CARE

By signing this authorization form ("Authorization"), I confirm I would like to enroll in the Program and authorize Chiesi USA, Inc., and its affiliates, service providers, agents, and successors (together, "Chiesi") to provide me with Program support. I authorize Chiesi, my healthcare providers, and their staff, my health plan, patient assistance programs, and my pharmacies to process and share my personal health information (such as information about my diagnosis, treatment, and lab results), personal identifying information (such as contact information and program preferences), and insurance information (such as prescriptions and plans) (together my "Information") in order to enroll me in the Program, provide Program support, administer the Program, meet legal obligations, conduct other business activities, and complete government reporting activities to Chiesi, its affiliated companies, vendors, agents, collaboration partners, and representatives (together, "Chiesi") including providers of alternate sources of funding for prescription drug costs, and other service providers supporting Chiesi Total Care (the "Program") for Healthcare Providers and patients for the purposes described below. For example, Chiesi may use my Information to communicate with me (such as by mail, phone, email, and text message*), tailor Program-related communications and services to my needs, and share my Information with my healthcare providers to dispense Chiesi products to me. Chiesi may also de-identify my Information, combine it with information about other patients, and use the results for Chiesi's and its affiliate's business purposes. I understand that once my Information is disclosed, my Information may no longer be protected by federal privacy laws and could be re-disclosed. However, Chiesi will only process and disclose my Information as described in this Authorization. Additional information on Chiesi's privacy practices can be found at <https://www.chiesiusa.com/privacy-policy/>.

For California Residents: By completing this form and submitting it for the purposes of enrollment in the Chiesi Total Care Program, you understand that Chiesi USA, Inc. may collect and use your Personal Information for the business purposes noted in the Chiesi Privacy Policy located at <https://www.chiesiusa.com/privacy-policy/>. To opt-out of the use of this Personal Information, you may email us at us.privacy@chiesi.com or by contact us via phone at 1-866-271-8587. Only you, or someone legally authorized to act on your behalf, may make an opt-out request. Please note that Chiesi USA, Inc does not sell or share Personal Information as defined in the California Consumer Privacy Act ("CCPA").

I understand that this Program is optional. I can refuse to sign this Authorization and refusing to sign will not affect my treatment, insurance coverage, or eligibility for benefits or Chiesi products. However, I understand that I need to sign this form to participate in the Program.

I understand that I may cancel this Authorization at any time or receive a copy of this Authorization by mailing a letter requesting cancellation to Chiesi Total Care, 8517 South Park Circle, Suite 200, Orlando, FL 32819. Upon cancellation, to the extent required by applicable law and personal data rights, Chiesi will no longer process my Information. I understand my cancellation will not apply to any of my Information already used or disclosed based on this Authorization prior to receipt of the cancellation. Unless canceled earlier, this Authorization expires ten (10) years from the date signed below, or as otherwise required by state or local law.

By signing below, I acknowledge that my pharmacy will receive payment from Chiesi for disclosing my Information to Chiesi. I acknowledge that if I am eligible for infusion co-pay assistance, the payment will be submitted to my healthcare facility where the infusion occurred. I acknowledge that if I am enrolled in a government-funded healthcare program, I am not eligible for and will not accept any co-pay assistance from Chiesi Total Care. I understand and agree that if my insurance information changes at any time while I am participating in the Chiesi Total Care Program, I will notify Chiesi Total Care as soon as possible, and any such change may affect my eligibility for such assistance programs.

By signing below, I also acknowledge that I have read and agree to the terms and conditions of the Chiesi Total Care support programs on page 2 of this document.

Feedback: We greatly appreciate your feedback. Please indicate whether you would like to be contacted by Chiesi about opportunities for you to provide feedback to us (such as Program feedback surveys or market research):

YES, I would like to be contacted to provide feedback. NO, I would not like to be contacted to provide feedback.

TEXT: Please indicate whether you authorize Chiesi to send text messages to the number(s) you provide. Your consent to receiving text messages is not a condition of receiving medication or services from Chiesi. I may also revoke my authorization to receive automated calls or text messages by replying STOP to any text from Chiesi Total Care or by contacting Chiesi Total Care in writing at the address above.

YES, I consent to receive text messages. NO, I do not consent to receive text messages.

Patient or Legal Guardian Signature: _____ **Signature Date (MM/DD/YY):** _____

Please specify any additional contacts with whom Chiesi Total Care is allowed to discuss your Information:

Additional Contact Name: _____ **Relationship to Patient:** _____

*Additional charges may apply. I understand that my telephone provider may charge me fees for calls or texts I receive, and I agree that Chiesi Total Care will not pay those fees.

Prescriber's Name (Print): _____

Name of Institution/Practice Name: _____

Office Contact Person: _____ **Office Phone:** _____



Patient Consent Form

Fax completed form to Chiesi Total CareSM at 1-833-746-2277 | Phone: 1-833-346-2277

CHIESI TOTAL CARE TERMS AND CONDITIONS

Chiesi Total Care Patient Support Services Program Terms and Conditions

To enroll in Chiesi Total Care (the "Program") and to assess eligibility for patient support services of the Program, patient must complete the Program Enrollment and Authorization Form and have a valid prescription for an eligible product of the Program. Additional documentation may be required. The patient must be a resident of the United States or one of its territories. If the patient is incapable of acting on their own behalf or if the patient is under 18 years old, enrollment into the Program may be completed by another person acting on their behalf (such as a caregiver).

A patient who receives healthcare benefits under any plan or program funded in whole or in part by federal or state governments including Medicare, Medicaid, TRICARE, Veterans Affairs (VA), State Prescription Assistance Plans (SPAPs) (other than health insurance for federal government employees), or any state healthcare program such as Medicaid, Children's Health Insurance Program, programs funded under Maternal and Child Health Program, or programs funded under Social Services Block Grant (collectively, "Government-funded Plans") are not eligible for the financial patient support services of the Program. A patient covered under a commercial health plan purchased through a health insurance marketplace or exchange is not a government-funded Plan beneficiary even if the costs of such coverage are subsidized by the federal government. If a change in prescription drug coverage should occur, the patient must notify the Program; such change may affect eligibility for the support services provided in the Program. Patients who have prescribed a product for an indication that is not consistent with the US Food and Drug Administration-approved labeling will not be eligible for financial patient support services offered through the Program.

Patients residing in or receiving treatment in certain states may not be eligible for certain patient support services of the Program. Patients may not seek reimbursement for value received from the Program. The Program does not obligate the use of any specific medication or healthcare provider. Patients who receive treatment or reside in Massachusetts, Michigan, Minnesota, or Rhode Island are not eligible for co-pay assistance for infusion services or routine testing services.

Chiesi Total Care may recommend contacting an independent financial assistance foundation. Independent financial assistance foundations have their own rules for eligibility. Chiesi USA does not fund independent financial assistance foundations, nor does Chiesi Total Care have involvement or influence in independent foundation decision making or eligibility criteria and does not know if a foundation will be able to help you. Chiesi Total Care can only refer you to a foundation that supports your disease state. This information is provided as a resource for you. Chiesi Total Care does not endorse or show preference for any foundation. The foundations recommended to you may not be the only ones that might be able to help you.

Chiesi Patient Education Liaisons ("PELs") may be available to assist you with disease education, provide relative educational or informational resources, and to answer questions you may have about your disease. Chiesi Field Reimbursement Managers ("FRMs") may be available to assist you with your product prescription drug coverage, including prior authorization, appeals, and denials.

PELs and FRMs are employees of Chiesi USA, Inc. PELs and FRMs are not healthcare providers and are not part of your healthcare team. PELs or FRMs will not provide medical care or advice. All treatment decisions should be made by you and your treating healthcare professional. To assist you, PELs and FRMs may need your information. If you choose to opt out of services by PELs and FRMs, you may do so at any time. Please see Chiesi's Privacy Policy at www.chiesiusa.com/privacy-policy/.

Program benefits may not be sold, purchased, traded, or offered for sale, purchase, or trade. The Chiesi Total Care patient support services are not valid where prohibited by law, taxed, or otherwise restricted. Offer subject to change or discontinuance without notice. Restrictions, including monthly maximums, may apply. This is not health insurance.

This is a voluntary program. Patients who choose not to enroll in the Program will be able to receive medication. Patients may participate in Chiesi Total Care without participating in a patient support services program of Chiesi Total Care. After enrolling in Chiesi Total Care, participants may opt out by contacting the Program, as outlined in the Chiesi Total Care Enrollment and Authorization Form. Patients must renew their eligibility by December 31 of each year to continue to receive support under the Program.

By participating in the Program, participants acknowledge that they understand and agree to comply with the Program Terms and Conditions.