

Market Applicability						
Market	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X

Mycapssa (octreotide)

Override(s)	Approval Duration
Prior Authorization	Initial approval duration: 6 months
Quantity Limit	Continuation approval duration: 1 year

Medications	Quantity Limit
Mycapssa (octreotide)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Mycapssa (octreotide) delayed-release capsules may be approved if the following criteria are met:

- I. Individual has a diagnosis with acromegaly; **AND**
- II. Individual has responded to and tolerated treatment with injectable octreotide or injectable lanreotide (defined as currently receiving a stable dose of either for at least the previous 3 months) (Label, Melmed 2015); **AND**
- III. Individual is using for long-term maintenance treatment.

Requests for continuation use of Mycapssa (octreotide) delayed-release capsules may be approved if the following criteria are met:

- I. Above criteria is met; **AND**
- II. Individual IGF-1 levels remain less than 1.3 X the upper limit of normal (ULN) and a serum growth hormone (GH) level less than 2.5 ng/ mL (Melmed 2015).

Key References:

1. Colao A, Grasso LFS, Giustina A, et al. Acromegaly [published correction appears in Nat Rev Dis Primers. 2019 Oct 21;5(1):72]. *Nat Rev Dis Primers*. 2019; 5: 20. Available at <https://www.nature.com/articles/s41572-019-0071-6.pdf>. Accessed July 15, 2020.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

CRX-ALL-0615-20

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability						
Market	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X

3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 14, 2020.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
6. Mycapssa (octreotide) delayed-release capsules for oral use. [Package Insert]. Chiasma; June 2020.
7. Melmed S, Popovic V, Bidlingmaier M, et al. Safety and efficacy of oral octreotide in acromegaly: results of a multicenter phase III trial [published correction appears in *J Clin Endocrinol Metab.* 2016; 101: 3863]. *J Clin Endocrinol Metab.* 2015;100(4):1699-1708.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.