

Acromegaly, Carcinoid, Cushing Syndrome Agents
Mycapssa (octreotide capsule)
Somavert (pegvisomant)
Signifor (pasireotide)
Signifor LAR (pasireotide injectable suspension)
Xermelo (telotristat ethyl)
Isturisa (osilodrostat)
Korlym (mifepristone 300 mg)
Recorlev (levoketoconazole)
Effective 06/05/2023

Plan	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		<input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
Exchange	Phone: 855-582-2022	Fax: 855-245-2134	
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	Signifor LAR is available through medical benefit only.		

Overview

Approval Diagnosis:

- Acromegaly - Signifor LAR[®], Somavert[®]
- Carcinoid syndrome diarrhea - Xermelo[®]
- Cushing's disease - Isturisa[®], Signifor[®], Signifor LAR[®]
- Hyperglycemia secondary to hypercortisolism in adult with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance - Korlym[®]

No PA	Require PA
Acromegaly Agents and Carcinoid Syndrome Agents	
Dopamine analogs (e.g., bromocriptine, cabergoline)	Mycapssa [®] (octreotide capsule)
Ianreotide	
Sandostatin [®] # (octreotide injection)	Signifor LAR [®] (pasireotide injectable suspension) ^{MB}
Sandostatin LAR [®] (octreotide injectable suspension)	
Somatuline [®] (lanreotide)	Somavert [®] (pegvisomant)
	Xermelo [®] (telotristat ethyl)

Cushing's Syndrome Agents	
ketoconazole tablet	Isturisa® (osilodrostat)
Lysodren® (mitotane)	Korlym® (mifepristone 300 mg)
	Recorlev® (levoketoconazole)
	Signifor® (pasireotide)
	Signifor LAR® (pasireotide injectable suspension) ^{MB}

This is a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting.

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Isturisa® (osilodrostat)

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of Cushing's disease
2. Appropriate dosing
3. **ONE** of the following:
 - a. Member has failed surgical intervention (reoccurrence after surgery or failed tumor removal)
 - b. Surgical interventions are not an option at this time
4. Physician documentation of inadequate response or adverse reaction to **ONE**, or contraindication to **ALL** of the following (Metopirone [metyrapone] is an acceptable trial):
 - a. cabergoline
 - b. ketoconazole tablet
 - c. Lysodren® (mitotane)
5. Physician documentation of inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following:
 - a. Signifor®
 - b. Signifor LAR®

Korlym® (mifepristone 300 mg)

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of hyperglycemia secondary to hypercortisolism in adult with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance
2. **ONE** of the following:
 - a. Member has failed surgical intervention (reoccurrence after surgery or failed tumor removal)
 - b. Surgical interventions are not an option at this time
3. Physician documentation of inadequate response, adverse reaction to **ONE**, or contraindication to **ALL** of the following (Metopirone [metyrapone] is an acceptable trial):
 - a. cabergoline
 - b. ketoconazole tablet
 - c. Lysodren® (mitotane)



4. Quantity requested is \leq 4 tablets/day

Mycapssa[®] (octreotide capsule)

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of acromegaly
2. Member is under the care of an endocrinologist
3. Paid claims or physician documentation that member has responded to and tolerated treatment with octreotide or lanreotide
4. Quantity requested is \leq 4 capsules/day

Recorlev[®] (levoketoconazole)

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of Cushing's syndrome
2. Appropriate dosing
3. **ONE** of the following:
 - a. Member has failed surgical intervention (reoccurrence after surgery or failed tumor removal)
 - b. Surgical interventions are not an option at this time
4. Physician documentation of inadequate response or adverse reaction to ketoconazole tablet
5. Physician documentation of inadequate response or adverse reaction to **ONE**, or contraindication to **BOTH** of the following (Metopirone [metyrapone] is an acceptable trial):
 - a. cabergoline
 - b. Lysodren[®] (mitotane)

Signifor[®] (pasireotide)

Signifor LAR[®] (pasireotide injectable suspension)

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of Cushing's disease
2. **ONE** of the following:
 - a. Member has failed surgical intervention (reoccurrence after surgery or failed tumor removal)
 - b. Surgical interventions are not an option at this time
3. Physician documentation of inadequate response, adverse reaction to **ONE**, or contraindication to **ALL** of the following (Metopirone [metyrapone] is an acceptable trial):
 - a. cabergoline
 - b. ketoconazole tablet
 - c. Lysodren[®] (mitotane)
4. **ONE** of the following:
 - a. For requests for Signifor[®], quantity requested is \leq 2 vials/day
 - b. For requests for Signifor LAR[®], quantity requested is \leq 1 kit or vial/30 days

Signifor LAR[®] (pasireotide injectable suspension)

Somavert[®] (pegvisomant)

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of acromegaly
2. Member is under the care of an endocrinologist
3. **ONE** of the following:
 - a. Member has persistent or recurring disease following surgery and/or radiation
 - b. Member is not a candidate for surgery
4. **ONE** of the following:



- a. Paid claims or physician documentation of inadequate response or adverse reaction to one somatostatin analog that does not require PA
 - b. Contraindication to the use of somatostatin analogs
5. **ONE** of the following:
- a. Member has moderate-to-severe disease symptoms
 - b. Member has mild disease and **ONE** of the following:
 - i. Paid claims or physician documentation of inadequate response or adverse reaction to one dopamine analog (e.g., cabergoline, bromocriptine) in combination with a somatostatin analog for overlap of 3 months within a 6-month period
 - ii. Adverse reaction to one somatostatin analog that does not require PA
 - iii. Contraindication to the use of dopamine analogs
6. **ONE** of the following:
- a. For requests for Signifor LAR[®], quantity requested is ≤ 1 kit or vial/30 days
 - b. For requests for Somavert[®], quantity requested is ≤ 1 vial/day

Xermelo[®] (telotristat ethyl)

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of carcinoid syndrome diarrhea
2. Physician documentation of inadequate response to one somatostatin analog therapy (e.g., octreotide or lanreotide)
3. Requested agent will be given in combination with somatostatin analog therapy (e.g., octreotide or lanreotide)
4. Quantity requested is ≤ 3 tablets/day

Continuation of Therapy

Isturisa, Korlym, Recorlev[®], and Signifor: Reauthorization requires physician documentation of a positive response to therapy as shown by clinical improvement or documented improvements in weight loss, blood pressure or glycemic measurements or improvement in urinary free cortisol.

Mycapssa, Signifor LAR, Somervert, and Xermelo: Reauthorization by physician will infer a positive response to therapy.

Limitations

1. Initial approvals will be granted for:
 - a. Xermelo: 6 months
 - b. All other agents: 12 months
2. Reauthorizations will be granted for:
 - a. Xermelo: 6 months
 - b. All other agents: 12 months.
3. The following quantity limits apply:

Signifor	60 vials per 30 days
Xermelo	90 tablets per 30 days
Somavert	30 vials per 30 days
Mycapssa	112 capsules per 28 days
Korlym	120 tablets per 30 days

References



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Review History

11/16/2022 – Created for Nov P&T. Matched MH UPPL. The following medications will require a prior authorization on the pharmacy benefit: Somavert, Signifor, Signifor LAR. Combined Mycapssa, Xermelo, Isturisa, Korlym, and Signifor LAR agents and matched MH UPPL criteria. Effective 2/1/23.

04/12/23 – Reviewed and updated for P&T. Added NTM drug, Recorlev. Clarified step through requirement for Isturisa. Effective 6/5/23.

