Mass General Brigham
Health Plan

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)
Effective 02/01/2023

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy when obtained through the pharmacy benefit		
Contact Information	**Medical and Specialty Medications**		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
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)
Sandostatin® # (octreotide injection)	Signifor LAR® (pasireotide injectable suspension)
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)
	Signifor® (pasireotide)
	Signifor LAR® (pasireotide injectable suspension)

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.

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, adverse reaction, or contraindication to Signifor® or 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 ≤ 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 ≤4 capsules/day

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 ≤ 2 vials/day
    b. For requests for Signifor LAR®, quantity requested is ≤ 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, 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.