

Pharmacy Policy

Givlaari – Unified Formulary

Policy Number: 9.338

Version Number: 1

Version Effective Date: 7/1/2021

Product Applicability		<input type="checkbox"/> All Plan+ Products
Well Sense Health Plan	Boston Medical Center HealthNet Plan	
<input type="checkbox"/> New Hampshire Medicaid	<input checked="" type="checkbox"/> MassHealth ACO	
	<input checked="" type="checkbox"/> MassHealth MCO	
	<input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct	
	<input type="checkbox"/> Senior Care Options	

Note: Disclaimer and audit information is located at the end of this document.

Policy

Reference Table:

Drugs that require PA	No PA
Givlaari® (givosiran) ^{PD}	

^{PD}Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

Procedure¹⁻³:

Approval Diagnosis:	Acute hepatic porphyria (AHP)
Approval Criteria	Prescriber provides documentation of ALL of the following:
Givlaari® (givosiran)	<ol style="list-style-type: none"> 1. Diagnosis of acute hepatic porphyria (AHP) 2. Member is ≥18 years of age 3. Member’s current weight (use to verify correct dosing; may take this information over the phone if missing on PA request) 4. Appropriate dosing
	<p><i>Note:</i></p> <ul style="list-style-type: none"> • <i>All prior authorization requests should have their decisions reported to the clinical reviewer of the day. Please see the Givlaari Monitoring</i>

	<i>Program Appendix for specifics regarding workflow.</i>
Denial Criteria:	Cases that do not meet the approval criteria will be denied. If a request is denied and the prescriber has additional clinical documentation, a new prior authorization request must be submitted.
Duration of Authorization:	Prior Authorization may be issued for one year .
Recertification Criteria:	Resubmission by prescriber will need to meet the following criteria and request can be recertified for one year : <ol style="list-style-type: none"> 1. Documentation of positive response to therapy 2. Updated member weight (use to verify correct dosing; may take this information over the phone if missing on PA request)

Appendix:

Stability

If prescriber is requesting Givlaari® (givosiran) for a member who is stable on the agent, the request should be reviewed using the recertification criteria listed in the procedure table above.

Grandfathering

Information is not applicable.

Additional Information

Requests for Off-Label Uses

Requests for off-label uses should be denied Non-FDA approved indication.

Compelling cases - Clinical and/or Supervisor Review

If clinical review/supervisor is not available and compliance is an issue, please forward to clinical review for follow-up.

Givlaari Monitoring Program Protocol and Procedures

Please refer to the Givlaari Monitoring Program Cover Sheet and Givlaari Annual Template for additional information.

Responsibility and Accountability

Policy History

Original Approval Date	Original Effective Date	Policy Owner	Approved by
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Original Approval Date	Original Effective Date	Policy Owner	Approved by
5/13/2021	7/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
5/13/2021	Created policy for MH Unified Formulary, policy date 3/1/21. Policy MA9.321_Givlaari discontinued as of 7/1/2021	7/1/2021	P&T Committee

Next Review Date

5/2022

Other Applicable Policies

References

Reference to Applicable Laws and Regulations, if Any
