BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

# Givlaari – Unified Formulary

**Policy Number:** 9.338
**Version Number:** 1
**Version Effective Date:** 7/1/2021

| Product Applicability | ☐ **All Plan+ Products** |
|---|---|
| **Well Sense Health Plan** | **Boston Medical Center HealthNet Plan** |
| ☐ New Hampshire Medicaid | ☒ MassHealth ACO |
| | ☒ MassHealth MCO |
| | ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct |
| | ☐ 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.

**Procedure[1-3]:**

| | |
|---|---|
| **Approval Diagnosis:** | Acute hepatic porphyria (AHP) |
| **Approval Criteria**<br><br>**Givlaari®** (givosiran) | Prescriber provides documentation of **ALL** of the following:<br>1. Diagnosis of acute hepatic porphyria (AHP)<br>2. Member is ≥18 years of age<br>3. Member's current weight (use to verify correct dosing; may take this information over the phone if missing on PA request)<br>4. Appropriate dosing<br><br>*Note:*<br>• ***All** prior authorization requests should have their decisions reported to the **clinical reviewer** of the day. Please see the Givlaari Monitoring* |

| | |
|---|---|
| | *Program Appendix for specifics regarding workflow.* |
| **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**:<br>1. Documentation of positive response to therapy<br>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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|---|---|---|---|
| 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