RxAdvance
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Clinical Policy Title:	mirvetuximab soravtansine-gynx
Policy Number:	RxA.804
Drug(s) Applied:	Elahere™
Original Policy Date:	01/17/2023
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Ovarian Cancer (must meet all):

1. Diagnosis of high-grade serous epithelial ovarian cancer, primary peritoneal cancer, or fallopian tube cancer;
2. Prescribed by or in consultation with an oncologist;
3. Member must be female and ≥ 18 years of age;
4. Member must have received at least one but no more than three prior systemic lines of anticancer therapy;
5. Member must have received bevacizumab prior to therapy;
6. Member's tumor must be positive for FRα expression as defined by the Ventana FOLR1 (FOLR-2.1) RxDx Assay;
7. Member must have an ECOG performance status of 0 or 1;
8. Request meets one of the following (a or b):*
   a. Dose does not exceed 6 mg/kg intravenously;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration
Commercial: 3 months
Medicaid: 3 months

II. Continued Therapy Approval

A. Ovarian Cancer (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or documentation supports that member is currently receiving Elahere™ for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
   a. Dose does not exceed 6 mg/kg intravenously;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).*

*Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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Commercial: 6 months
Medicaid: 6 months

References
Not Applicable

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	12/13/2022	01/17/2023
Policy was reviewed.	10/19/2023	10/19/2023

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