

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: May 15, 2024

OFF-LABEL ID #: 2656

DRUG NAME: Selinexor

OFF-LABEL USE: Malignant neoplasm of endometrium of corpus uteri Metastatic or recurrent, as maintenance therapy

COMPENDIA TRANSPARENCY REQUIREMENTS	
1	Provide criteria used to evaluate/prioritize the request (therapy)
2	Disclose evidentiary materials reviewed or considered
3	Provide names of individuals who have substantively participated in the review or disposition of the request and disclose their potential direct or indirect conflicts of interest
4	Provide meeting minutes and records of votes for disposition of the request (therapy)

EVALUATION/PRIORITIZATION CRITERIA: C,R, S *to meet requirement 1

CODE	EVALUATION/PRIORITIZATION CRITERIA
A	Treatment represents an established standard of care or significant advance over current therapies
C	Cancer or cancer-related condition
E	Quantity and robustness of evidence for use support consideration
L	Limited alternative therapies exist for condition of interest
P	Pediatric condition
R	Rare disease
S	Serious , life-threatening condition

Note: a combination of codes may be applied to fully reflect points of consideration [eg, therapy may represent an advance in the treatment of a life-threatening condition with limited treatment alternatives (ASL)]

EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	LITERATURE CODE
Vergote I, Pérez-Fidalgo JA, Hamilton EP, et al. Oral Selinexor as Maintenance Therapy After First-Line Chemotherapy for Advanced or Recurrent Endometrial Cancer. <i>J Clin Oncol</i> . 2023;41(35):5400-5410. doi:10.1200/JCO.22.02906	S
Vergote I, Perez Fidalgo A, Valabrega G, et al. ENGOT-EN20/GOG-3083/XPORT-EC-042 - A phase III, randomized, placebo-controlled, double-blind, multicenter trial of selinexor in maintenance therapy after systemic therapy for patients with p53 wild-type, advanced, or recurrent endometrial carcinoma: rationale, methods, and trial design. <i>Int J Gynecol Cancer</i> . Published online April 16, 2024. doi:10.1136/ijgc-2024-005412	S
Vergote IB, Lund B, Peen U, et al. Phase 2 study of the Exportin 1 inhibitor selinexor in patients with recurrent gynecological malignancies. <i>Gynecol Oncol</i> . 2020;156(2):308-314. doi:10.1016/j.ygyno.2019.11.012	1

Literature evaluation codes: S = Literature selected; 1 = Literature rejected = Topic not suitable for scope of content; 2 = Literature rejected = Does not add clinically significant new information; 3 = Literature rejected = Methodology flawed/Methodology limited and unacceptable; 4 = Other (review article, letter, commentary, or editorial)

CONTRIBUTORS:

*to meet requirement 3

PACKET PREPARATION	DISCLOSURES	EXPERT REVIEW	DISCLOSURES
Stacy LaClaire, PharmD	None		
Catherine Sabatos, PharmD	None		
		John D Roberts	None
		Jeffrey Klein	None
		Richard LoCicero	Incyte Corporation Local PI for REVEAL. Study is a multicenter, non-interventional, non-randomized, prospective, observational study in an adult population for patients who have been diagnosed with clinically overt PV and are being followed in either community or academic medical centers in the US who will be enrolled over a 12-month period and observed for 36 months.

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MERATIVE MICROMEDEX	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases		B
Todd Gersten	Evidence is Inconclusive	Class IIb: Recommended, in Some Cases	Selinexor has demonstrated limited efficacy as a maintenance therapy in endometrial cancer. PFS was significantly improved only in patients without TP53 mutations, and overall survivorship in this specific cohort has not been reported.	
Jeffrey Klein	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	The use of Selinexor to treat 2nd line endometrial cancer patients showed a superior progression free survival over placebo in a trial. It appears that selinexor works more favorably in patients that demonstrated a particular biomarker. Some higher grade adverse effects required dose modifications.	

Howard Goodman	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	<p>The study cited is a phase 3 randomized trial studying Selinexor as maintenance therapy for women with advanced or recurrent endometrial cancer who exhibited a complete or partial response after treatment with first line platinum-taxane chemotherapy. The study demonstrated a trend towards improved PFS, 5.7 vs 3.8 months on the experimental arm, p=.126 which did not reach significance. In a prespecified exploratory analysis, maintenance therapy with Selinexor did achieve statistically significant benefit in PFS in women whose tumors demonstrated wild type TP53-13.7 vs 3.7 months, p=.049. Adverse events were judged to be acceptable and manageable. The study would suggest benefit for Selinexor as maintenance therapy for women with recurrent or advanced endometrial cancer whose tumors express wild type TP53. Further phase 3 trials are ongoing</p>	
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