selinexor (Xpovio™)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO086

Description

Selinexor (Xpovio) is an orally nuclear export inhibitor.

Length of Authorization

N/A

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit	DDID
selinexor (Xpovio)	80 mg tablet twice weekly carton	Relapsed or refractory multiple myeloma	N/A	207237
	100 mg tablet once weekly carton		N/A	207238
	80 mg tablet once weekly carton		N/A	207236
	60 mg tablet once weekly carton		N/A	207235

Initial Evaluation

I. Selinexor (Xpovio) is considered investigational when used for all conditions, including but not limited to multiple myeloma.

Renewal Evaluation

N/A

Supporting Evidence

I. Selinexor (Xpovio) was evaluated in one, Phase 2, open-label trial of 79 patients in combination with dexamethasone only. No other oncolytic therapies were included in the drug regimen. Patients included were relapsed, refractory, or intolerant to bortezomib, carfilzomib, lenalidomide and pomalidomide. Some patients were also refractory to daratumumab. The primary endpoint was objective response rate (ORR), which occurred in 21%. Secondary outcomes included progression free survival (PFS) and overall survival (OS), which resulted in 2.3 and 9.3 months, respectively. Selinexor (Xpovio) was approved via the accelerated approval

pathway, and continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials.

II. The safety profile is as follows: 60% of patients in the trial experiencing grade 3-4 adverse events, including thrombocytopenia, anemia, and neutropenia. Additionally, other serious adverse events occurred such as febrile neutropenia, serious infections, and fatal serious bleeding.

Investigational or Not Medically Necessary Uses

I. Multiple myeloma
   A. The quality of the current evidence for selinexor (Xpovio) is considered low. The primary outcome, ORR, has not yet been correlated to clinically meaningful outcomes such as overall survival or quality of life parameters in MM. The PFS and OS result have unknown value due to the single arm as well as the open-label design, and the medication has a significant safety profile. There is a lack of evidence indicated that selinexor (Xpovio) would provide a net health benefit for members. Additionally, treatment guidelines for MM specify use of a three drug regimen is preferred when available and appropriate (e.g., the member is not elderly or frail), and to utilize at least two new therapies compared to previous regimens if possible. Selinexor (Xpovio) has not been sufficiently studied in this space. Trials evaluating as a part of a triple regimen were underway as of August 2019, further clinical evaluation of safety and efficacy are needed to confirm a net health benefit and place in therapy for this medication.

References

1. Xpovio [Prescribing Information]. Karyopharm therapeutics Inc. Newton, MA. July 2019.
2. National Comprehensive Cancer Network NCCN Guidelines: Multiple Myeloma 3.2019. June 2019. Available at https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed August, 2019.
3. Vogl DT, Dingli D, Cornell RF, et al. Selective Inhibition of Nuclear Export With Oral Selinexor for Treatment of Relapsed or Refractory Multiple Myeloma. J Clin Oncol. 2018;36(9):859-866.
4. IPD Analytics. Xpovio (selinexor) New Drug Approval. Published August 2019.
5. FDA Advisory Committee Meeting Introductory Comments. NDA 212306 selinexor. February 2019. Available at https://www.fda.gov/media/121670/download. Accessed August, 2019.
6. Mikhael J, Ismaila N, Cheung MC, et al. Treatment of Multiple Myeloma: ASCO and CCO Joint Clinical Practice Guideline. J Clin Oncol. 2019;37(14):1228-1263.

Policy Implementation/Update:

Date Created	August 2019
Date Effective	November 2019
Last Updated	
Last Reviewed	

Action and Summary of Changes	Date