PANOBINOSTAT

Generic	Brand	HICL	GCN	Exception/Other
PANOBINOSTAT	FARYDAK	41794		ROUTE = ORAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of multiple myeloma and meets **ALL** of the following criteria?
   - The patient has been treated with at least 2 prior regimens, including Velcade (bortezomib) and an immunomodulatory agent, such as Thalomid, Revlimid, or Pomalyst
   - The requested agent will concurrently be used with Velcade (bortezomib) and dexamethasone

   If yes, **approve for 12 months by HICL for #6 capsules per 21 days with a fill count of 8 (8 cycles).**
   If no, do not approve.
   DENIAL TEXT: Our guideline for **PANOBINOSTAT (Farydak)** requires that the patient has a diagnosis of multiple myeloma. The following criteria must also be met.
   - The patient has been treated with at least 2 prior regimens, including Velcade (bortezomib) and an immunomodulatory agent, such as Thalomid, Revlimid, or Pomalyst
   - The requested agent will concurrently be used with Velcade (bortezomib) and dexamethasone

RENEWAL CRITERIA

1. Has the patient tolerated the first 8 cycles of therapy without any severe or medically significant toxicity?

   If yes, **approve for 12 months by HICL for #6 capsules per 21 days with fill count of 8 (8 cycles).**
   If no, do not approve.
   DENIAL TEXT: Our guideline for **PANOBINOSTAT (Farydak)** renewal requires that the patient has tolerated therapy without experiencing any severe or medically significant toxicity.

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RATIONALE

Promote appropriate utilization of **Farydak (panobinostat)** based on FDA approved indication. Initial dosing for up to 8 cycles. Renewal provided for patients with clinical benefit who do not experience unresolved severe or medically significant toxicity (maximum duration of therapy up to 16 cycles which allows up to 96 capsules in 48 weeks).

The most common prior antineoplastic therapies in the PANORAMA-1 (Panobinostat Oral in Multiple Myeloma) trial were corticosteroids (90%), melphalan (80%), thalidomide (53%), cyclophosphamide (47%), bortezomib (44%), and lenalidomide (19%).

Given the toxicity concerns, a regimen containing Farydak may be less preferred over other regimens for relapsed/refractory MM. As of March 2015, the NCCN lists the following as Category 1 recommendations (please check NCCN treatment guidelines for other possible regimens):

- Velcade
- Velcade with liposomal doxorubicin (i.e. Doxil, Lipodox)
- Revlimid/dexamethasone
- Kyprolis (carfilzomib)/Revlimid/dexamethasone

Farydak might also be reserved for patients less than 65 years of age with good performance status who either have not been exposed to or have been exposed to, but are not refractory to, proteasome inhibitors (i.e. Velcade and Kyprolis).

DOSAGE

The recommended starting dose of Farydak is 20 mg, taken orally once every other day for 3 doses per week in Weeks 1 and 2 of each 21-day cycle for up to 8 cycles. Consider continuing treatment for an additional 8 cycles for patients with clinical benefit who do not experience unresolved severe or medically significant toxicity. The total duration of treatment may be up to 16 cycles (48 weeks). Farydak is administered in combination with bortezomib and dexamethasone.

21-Day Cycle														
Cycles 1 to 8 (3-Week cycles)	Week 1 Days							Week 2 Days						Week 3
FARYDAK	1		3		5			8		10		12		Rest period
Bortezomib	1			4				8			11			Rest period
Dexamethasone	1	2		4	5			8	9		11	12		Rest period

FDA APPROVED INDICATION

Indicated in combination with bortezomib and dexamethasone for the treatment of patients with multiple myeloma who have received at least 2 prior regimens, including bortezomib and an immunomodulatory agent.

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REFERENCES

- Farydak [Prescribing Information]. East Hanover, NJ: Novartis; February 2015.
- NCCN Clinical Practice Guideline in Oncology: Multiple Myeloma Version 3.2015. National Comprehensive Cancer Network. Available at: http://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf [Accessed February 23, 2015].

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/01/16
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