Health Net®

Prior Authorization Protocol

FARYDAK® (panobinostat)

NATL

Coverage of drugs is first determined by the member's pharmacy or medical benefit. Please consult with or refer to the Evidence of Coverage document.

I. FDA Approved Indications:

- In combination with bortezomib (Velcade®) and dexamethasone, for the treatment of patients with multiple myeloma who have received at least 2 prior regimens, including bortezomib (Velcade®) and an immunomodulatory agent

II. Health Net Approved Indications and Usage Guidelines:

- Diagnosis of multiple myeloma (MM)

  AND

- Failure or clinically significant adverse effects to at least 2 prior regimens including Velcade® and an immunomodulatory agent (e.g., dexamethasone)

III. Coverage is Not Authorized For:

- Non-FDA approved indications, which are not listed in the Health Net Approved Indications and Usage Guidelines section, unless there is sufficient documentation of efficacy and safety in the published literature.

IV. General Information:

- Accelerated FDA approval for this indication is based on progression free survival. Its continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials.
- According to National Comprehensive Cancer Network guideline, category 1 recommendation for the treatment of multiple myeloma is listed as follows: a) maintenance therapy when in remission: Revlimid®, Thalomid®, and b) therapy for previously treated MM: Velcade®, Velcade®/liposomal doxorubicin, Kyprolis™/Revlimid®/dexamethasone, Revlimid®/dexamethasone. Therapy for previously treated relapsed/refractory MM is considered in the following conditions: patients with relapsed disease after allogeneic or autologous stem cell transplant (SCT), patients with primary progressive disease after initial allogeneic or autologous SCT, and patients with ineligible for SCT with progressive or relapsing disease after initial primary therapy.
- Because of severe diarrhea and cardiac toxicities, Farydak has a Risk Evaluation and Mitigation Strategy (REMS) program that consists of a Medication Guide and a Dear Healthcare Professional Letter. Patient and physician enrollment in the manufacturer's REMS program is required.
- Farydak is currently being studied for the treatment of myelodsyplastic syndrome, acute myeloid leukemia, myelofibrosis, refractory Hodgkin's lymphoma, advanced solid tumors (breast, brain, prostate), non-small cell lung cancer, chronic myelogenous leukemia, and renal cell carcinoma.

V. Therapeutic Alternatives:

Drug	Dosing Regimen	Dose/Limit/Maximum Dose

Draft Prepared: 03.01.15 R.Olegario
Approved by Health Net Pharmacy & Therapeutics Committee: 05.06.15,11.18.15
Revised: 6.30.15 DTeng, 01.07.16 J Stansberry

Drug	Dosing Regimen	Dose/Limit/Maximum Dose
dexamethasone (pulse dose as single agent)	**Multiple Myeloma (Conventional primary therapy)** Dexamethasone: 40 mg PO days 1-4, 9-12, 17-20	As recommended in dosing regimen
Pomalyst® (pomalidomide) *	**Multiple Myeloma** 4 mg PO QD on days 1-21 of repeated 28-day cycles until disease progression. Pomalyst may be given in combination with dexamethasone Avoid Pomalyst in patients with a serum creatinine greater than 3.0 mg/dL	As recommended in dosing regimen
Revlimid® (lenalidomide) */dexamethasone	**Multiple Myeloma** Revlimid: 25 mg PO QD on days 1-21 of repeated 28 day cycles Dexamethasone: 40 mg PO QD on days 1-4,9-12,17-20 of each 28 day cycle for the first 4 cycles then 40 mg PO QD for days 1-4 every 28 days	As recommended in dosing regimen
Thalomid® (thalidomide)/ dexamethasone	**Multiple Myeloma** Thalomid: 200 mg PO QD Dexamethasone: 40 mg PO QD on days 1-4,9-12,17-20 of every 28 day treatment cycle	As recommended in dosing regimen
melphalan/prednisone (MP)	**Multiple Myeloma (Conventional primary therapy)** Melphalan: 0.25 mg/kg/day PO for 4 days or 0.2 mg/kg/day PO for 5 days Prednisone: 2 mg/kg/day PO for 4 days Repeat every 4 to 6 weeks	As recommended in dosing regimen
vincristine/doxorubicin/dexamethasone (VAD)*	**Multiple Myeloma (Conventional primary therapy)** Vincristine: 0.4 mg/day (Max 2 mg) IV	As recommended in dosing regimen

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Drug	Dosing Regimen	Dose/Limit/Maximum Dose
	continuous infusion on days 1-4 Doxorubicin: 9 mg/m^2/day IV continuous infusion on days 1-4 Dexamethasone: 40 mg PO QD on days 1-4, 9-12, 17-20 Repeat cycle every 25-35 days	
Velcade (bortezomib) *	**Multiple Myeloma** 1.3 mg/m^2 IV bolus or SC twice weekly, with at least 72 hours between doses (on days 1, 4, 8, 11, 22, 25, 29, and 32), for cycles 1 to 4; then once weekly for 6 weeks (on days 1, 8, 22, and 29) for cycles 5 through 9 Retreatment may be considered for patients with MM who had previously responded to treatment with Velcade and who have relapsed at least 6 months after completing prior Velcade treatment.	As recommended in dosing regimen
Kyprolis (carfilzomib) *	**Multiple Myeloma** 20 mg/m^2 IV on two consecutive days each week for 3 weeks (Days 1, 2, 8, 9, 15 and 16) followed by a 12-day rest period (Days 17 to 28). Each 28-day period is considered one treatment cycle. If tolerated in cycle 1, the dose should be escalated to 27 mg/m^2 and in the subsequent cycles.	As recommended in dosing regimen

*Requires Prior Authorization

VI. Recommended Dosing Regimen and Authorization Limit:

Drug	Dosing Regimen	Authorization Limit
Farydak	20 mg PO QOD for 3 doses per week (on Days 1, 3, 5, 8, 10,	Length of Benefit

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Drug	Dosing Regimen	Authorization Limit
	and 12) of Weeks 1 and 2 of each 21-day cycle for 8 cycles Reduce the starting dose of Farydak to 15 mg in patients with mild hepatic impairment and 10 mg in patients with moderate hepatic impairment or when coadministered with strong CYP3A inhibitors	or until disease progression

VII. Product Availability:

Capsule: 10 mg, 15 mg, 20 mg

VIII. References:

1. Farydak [package insert]. East Hanover, MJ: Novartis Pharmaceuticals; February 2015.
2. National Comprehensive Cancer Network. Multiple Myeloma Version 2.2016. Available at: http://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed January 7, 2016.
3. Clinical Pharmacology Web site. Available at: http://clinicalpharmacology-ip.com/default.aspx. Accessed January 7, 2016.
4. Farydak. American Hospital Formulary Service Drug Information. Available at https://medicinescomplete.com/mc/ahfs/current/. Accessed January 7, 2016.
5. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 7, 2016.
6. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at http://www.nccn.org/professionals/drug_compendium. Accessed January 8, 2016.

The materials provided to you are guidelines used by this health plan to authorize, modify, or determine coverage for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual needs and the benefits covered under your contract.

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