Market Applicability															
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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Kyprolis (carfilzomib)

DRUG.00053

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Kyprolis (carfilzomib)

APPROVAL CRITERIA

Requests for Kyprolis (carfilzomib) may be approved for the treatment of Multiple Myeloma when the following criteria are met:

I. Multiple Myeloma (for primary treatment)
   A. Individual has a diagnosis of multiple myeloma; **AND**
   B. Individual does not have New York Heart Association (NYHA) class III or IV heart failure; **AND**
   C. Kyprolis (carfilzomib) is being used in combination with lenalidomide plus dexamethasone;

OR

II. Multiple Myeloma (for relapsed or refractory disease)
   A. Individual has a diagnosis of multiple myeloma; **AND**
   B. Individual does not have New York Heart Association (NYHA) class III or IV heart failure; **AND**
   C. Kyprolis (carfilzomib) is being used:
      1. In combination with dexamethasone with or without lenalidomide when the individual has received one to three prior lines of therapy; **OR**
      2. As a single agent when the individual has received one or more prior lines of therapy; **OR**
      3. In combination with panobinostat when the individual has received at least two prior therapies including bortezomib and an immunomodulatory agent (for example, lenalidomide or thalidomide).

Requests for Kyprolis (carfilzomib) may be approved for the treatment of Waldenström's macroglobulinemia when the following criteria are met:

Market Applicability															
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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I. Kyprolis (carfilzomib) is being used as a primary agent, in combination with rituximab and dexamethasone; **OR**
II. Kyprolis (carfilzomib) is being used for relapsed disease when the primary therapy of carfilzomib, rituximab, and dexamethasone was given and relapse is greater than 12 months after therapy.

Requests for Kyprolis (carfilzomib) may **not** be approved when the above criteria are not met.

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

1. Carfilzomib (systemic). In: DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically. Available at: http://www.micromedexsolutions.com. Accessed on April 12, 2018.
2. Kyprolis (carfilzomib) [Product Information]. South San Francisco, CA. Onyx Pharmaceuticals. January 17, 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/202714s017lbl.pdf. Accessed on April 12, 2018.
3. National Cancer Institute. Common terminology criteria for adverse events. Version 4.03. June 2010. Available at: https://www.eortc.be/services/doc/ctc/CTCAE_4.03_2010-06-14_QuickReference_5x7.pdf. Accessed on April 12, 2018.
4. National Comprehensive Cancer Network®. NCCN Drugs & Biologic Compendium™ (electronic version). For additional information visit the NCCN website: http://www.nccn.org. Accessed on April 12, 2018.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2018 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on April 12, 2018.
    - Multiple Myeloma (V.4.2018). Revised February 12, 2018.
    - Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma (V.1.2018). Revised March 7, 2018.